IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE ALLEGATIONS AND DEFENSES IN DEFENDANT'S ANSWER AND COUNTERCLAIM

APPENDIX OF UNPUBLISHED CASES

App. 1 *Spencer v. Dawson*, No. 04 C 5048, 2005 WL 643331 (N.D. Ill. Mar. 3, 2005)

App. 2 *Extra Equipamentos E Exportacao Ltda. v. Case Corp.*, No. 01 C 8591, 2005 WL 843297 (N.D. Ill. Jan. 20, 2005)

App. 3 *Duramed Pharms., Inc. v. Wyeth-Ayerst Labs., Inc.*, No. C-1-00-735, slip op. (S.D. Ohio Aug. 1, 2001)

App. 4 *Genderm Corp. v. Biozone Labs.*, No. 92 C 2533, 1992 WL 220638 (N.D. Ill. Sept. 3, 1992)

App. 5 *Ehrhart v. Synthes*, No. 07-01237, 2007 WL 4591276 (D.N.J. Dec. 28, 2007)

App. 6 *Ace Hardware Corp. v. Marn, Inc.*, No. 06 C5335, 2006 WL 4007863 (N.D. Ill. Dec. 27, 2006)

APPENDIX 1

HSpencer v. Dawson
N.D.Ill.,2005.
Only the Westlaw citation is currently available.
United States District Court,N.D. Illinois, Eastern Division.
Steven K. SPENCER, Plaintiff,
v.
Officer Jospeh DAWSON, et al., Defendants.
No. 04 C 5048.

March 3, 2005.

John P. De Rose, Anthony T. Capua, Jessica Rae Hill, John P. Derose & Associates, Hinsdale, IL, for Plaintiff.
Lance C. Malina, James Vincent Ferolo, Jacob Henry Karaca, Klein, Thorpe & Jenkins, Ltd., Chicago, IL, for Defendants.

MEMORANDUM AND ORDER

MANNING, J.
***1** Plaintiff Steven Spencer, who is deaf, was charged with resisting arrest and assaulting a peace officer. After he was acquitted, he filed suit against the Village of Wheeling and the Wheeling police officers who had arrested him, asserting that the officers used excessive force, violated the Fourth and Fourteenth Amendments by entering his home without a warrant, intentionally inflicted emotional distress upon him, and violated § 504 of the Rehabilitation Act, 29 U.S.C. § 794, which outlines the responsibilities of law enforcement personnel when dealing with hearing impaired individuals. The defendants seek to dismiss or strike portions of Spencer's complaint. For the following reasons, the motion is granted in part and denied in part.

I. Background

For the purposes of this opinion, the court will accept the allegations of the complaint as true. Plaintiff Steven Spencer is deaf and communicates primarily through the use of sign language. He taught himself to speak and can occasionally read the lips of people who speak to him. He also uses a teletypewriter (TTY) device attached to his telephone. Spencer and his former girlfriend, Aliza Meyer, who is also deaf, co-owned a trailer home in Wheeling, Illinois.[FN1]

FN1. Because Aliza Meyer's father is a central figure in the events underlying Spencer's complaint, the court will refer to Aliza using her first name to avoid confusion between the two Meyers.

On March 25, 2003, Spencer was "peacefully ensconced" in the trailer when Aliza's father arrived uninvited and unannounced. Meyer told Spencer that he had not called ahead because he wanted to "force the issue" of selling the trailer since Spencer and Aliza had split up. Aliza subsequently came over and began to argue with Spencer. Meyer ordered his daughter to leave and the already heated conversation between the two men escalated until Spencer ordered Meyer to leave.

When Meyer refused to do so, Spencer called 911 using the TTY device attached to his phone. This caused Meyer to leave the trailer. Spencer stayed on the line with the 911 operator until the police arrived. In approximately five to ten minutes, Officers Dawson and Conway entered the trailer accompanied by Meyer. Spencer was very distressed at Meyer's reappearance in the trailer and immediately told Meyer to leave.

According to Spencer, the police were dismissive of his feelings about Meyer's presence in the trailer and thus made the "heartless" suggestion that Meyer should stay and help Spencer read their lips. In response, Spencer told the officers he could communicate by himself. The officers then ordered Meyer to leave and "cavalierly asked [Spencer] what he wanted to do about the situation."Spencer advised the officers that he wanted to file a charge of trespass against Meyer.

The officers left the trailer to speak with Meyer, who was outside. As time passed, Spencer began to pace back and forth in the trailer and became progressively more agitated. After approximately fifteen minutes, the officers entered the trailer with Aliza. Conway grabbed Spencer's arm and spoke to him. Spencer

paid close attention to Conway's lips to make sure that Conway was not placing him under arrest. When he realized Conway was telling him to calm down, Spencer broke free and resumed his pacing. Spencer walked approximately six feet from Conway and said, using sign language and his voice, "You just assaulted me!"

***2** Conway's face turned red and he began to angrily speak to Spencer. Spencer could not understand Conway because Conway was speaking too fast, but was dissatisfied with the officers and told them to leave, again using sign language and his voice. Conway then "used his presence in an intimidating manner" and "kept trying to get into Spencer's face, saying something repeatedly."Spencer eventually figured out that Conway was telling him to put his hands down and signed, "No! I have a right to sign! And you just assaulted me!"

Conway and Dawson conferred and Dawson sprayed Spencer with pepper spray. The officers left while the spray settled and Spencer attempted to telephone for medical assistance as his eyes were swollen shut from the spray and he was in great pain. Officer McInerney, another officer who had been summoned to the scene, entered the trailer with Conway and Dawson. Spencer pleaded with the officers not to hurt him, but the officers nevertheless slammed him to the floor, brutally battered him, and handcuffed him. Spencer attempted to extend his palms out behind him so someone could sign into them and tell him what was happening, but no one did so.

Spencer sensed that he was being removed from the trailer on a gurney and continued to panic since he did not know where he was going or what was happening. He was strapped down to the gurney and taken to an unknown location. Eventually, someone signed into his hand and told him he was at the hospital and would receive eye drops. Feeling safer due to his ability to communicate, Spencer cooperated, received the drops, and had the restraints removed.

Kim, the hospital employee who was speaking with Spencer using sign language, asked Spencer if he knew he was under arrest. Spencer told her he did not know this and asked Kim to find out what the charges were. The officers refused to tell Kim, stating that Spencer would receive an explanation at the Wheeling Police Station. The hospital advised the officers that they had to handcuff Spencer with his hands in front of him so he could communicate and after some delay, the officers did so.

At the police station, Spencer had difficulty communicating with the officers but eventually understood that he had been charged with resisting arrest and assaulting a peace officer. He did not, however, understand the basis of the charges. The officers were unable to communicate effectively with him and instead pointed at their ears as if to indicate that Spencer should listen to them speak. After a jury trial, Spencer ultimately was acquitted of all charges.

In his four count complaint, Spencer alleges that: (1) the officers violated § 1983 by using excessive force and entering his trailer without a warrant and wrongfully arresting him in violation of the Fourth and Fourteenth Amendments; (2) the Village of Wheeling is liable under § 1983 because it failed to properly train and supervise its officers pursuant to a custom, policy, or practice of disregarding the rights of hearing-impaired residents; (3) the officers intentionally inflicted emotional distress in violation of state law; and (4) the officer and the Village of Wheeling are liable under § 504 of the Rehabilitation Act, 29 U.S.C. § 794, which outlines the responsibilities of law enforcement personnel when dealing with hearing impaired individuals, because they failed to provide him with an interpreter or communicate with him in the manner prescribed by the Rehabilitation Act. The defendants have moved to dismiss portions of Spencer's complaint and to strike certain paragraphs as impertinent and prejudicial.

II. Discussion

A. Motion to Dismiss

1. Standard on 12(b)(6) Motion to Dismiss

***3** In ruling on a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), the court must assume the truth of all facts alleged in the complaint, construing the allegations liberally and viewing them in the light most favorable to the plaintiff. *See, e.g., McMath v. City of Gary,* 976 F.2d 1026, 1031 (7th Cir.1992). Dismissal is properly granted only if it is clear that no set of facts which the plaintiff could prove consistent

with the pleadings would entitle the plaintiff to relief. *Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). However, the court is neither bound by the plaintiff's legal characterization of the facts, nor required to ignore facts set forth in the complaint that undermine the plaintiff's claims.*Scott v. O'Grady,* 975 F.2d 366, 368 (7th Cir.1992).

2. § 1983 Claims Against the Village of Wheeling

To state a § 1983 claim against a municipality, a complaint must allege that a constitutional deprivation was caused by an official policy or custom. *See, e.g., Monell v. Dep't of Soc. Servs. of the City of N.Y.,* 436 U.S. 658, 690, 98 S.Ct. 2018, 56 L.Ed.2d 611 (1978). Thus, a governmental entity violates § 1983:(1) if it has an express policy that, when enforced, causes constitutional deprivation; (2) if there is a widespread practice that, although not authorized by written law or express municipal policy, is so permanent and well settled as to constitute custom or usage with the force of law; (3) if a person with final policymaking authority causes a constitutional injury. *See McTigue v. City of Chicago,* 60 F.3d 381, 382 (7th Cir.1995).

The defendants contend that Spencer's § 1983 claims against the Village of Wheeling are deficient because they are conclusory and, in any event, a single incident of unconstitutional conduct allegedly perpetrated pursuant to an unconstitutional policy, custom, or practice of a governmental entity is not enough to state a claim under § 1983.

a. Are Spencer's § 1983 Claims Against the Village of Wheeling Sufficiently Detailed?

Consideration of the defendants' argument regarding the complaint's level of specificity necessarily begins with the Supreme Court's decision in *Leatherman,* which rejected attempts to impose a heightened pleading standard for § 1983 claims and held that notice pleading is sufficient. *Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit,* 507 U.S. 163, 168, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993). "Notice pleading," however, is not synonymous with conclusory statements. As the Seventh Circuit has explained:

Although Fed.R.Civ.P. 8 does not require detailed factual pleading, a plaintiff's assertions must still direct the defendant to the factual cause of the plaintiff's alleged injury. "Boilerplate allegations of a municipal policy, entirely lacking in any factual support that a [municipal] policy does exist, are insufficient.... The absence of any facts at all to support plaintiff's claim renders the allegations mere legal conclusions of section 1983 liability devoid of any well-pleaded facts."

4McTigue v. City of Chicago,* 60 F.3d at 382,*quoting Baxter by Baxter v. Vigo County School Corp.,* 26 F.3d 728, 736 (7th Cir.1994).

Here, Spencer's complaint contains exceptionally extensive facts regarding the events on the day of his arrest. In contrast, the allegations regarding the alleged existence of the Village of Wheeling's official policy regarding arrests of individuals in similar circumstances to Spencer's are conclusory. Specifically, Spencer simply states that the Village of Wheeling failed to properly train and supervise the defendant officers "on when the use of ... force is necessary and/or appropriate, which evinces a custom, policy, or practice by the Village of Wheeling" and that the malicious and unconstitutional actions of the defendant officers show a "policy, practice and custom of encouraging and condoning such acts."

Thus, Spencer is essentially arguing that the Village of Wheeling by definition must have an unconstitutional policy because the Village's officers allegedly violated his rights. This argument is not enough to state a claim under § 1983 as it is based on a supposition as opposed to any actual factual allegations regarding the existence of an official policy. The court stresses that it is not imposing a fact-pleading requirement on Spencer. He can plead conclusions, but those "conclusions must provide the defendant[s] with at least minimal notice of the claim."*Jackson v. Marion County,* 66 F.3d 151, (7th Cir.1995); *see also Doherty v. City of Chicago,* 75 F.3d 318, 326 (7th Cir.1996) ("something more than a conclusory allegation is necessary.... Still there must be sufficient facts pleaded to allow the court and the defendants to understand the gravamen of the plaintiff's complaint"); *McTigue v. City of Chicago,* 60 F.3d at 382-83 ("Boilerplate allegations of a municipal policy, entirely lacking in any factual support that a [municipal] policy does exist, are insufficient"). Thus, Spencer's § 1983 claims against

the Village of Wheeling are dismissed without prejudice.

b. Can a Single Incident of Allegedly Unconstitutional Conduct Constitute a Custom, Policy, or Practice?

The court anticipates that Spencer will attempt to amend the allegations against the Village of Wheeling so the court will address the Village's alternative argument in the interests of judicial efficiency. According to the defendants, a single incident of unconstitutional conduct allegedly perpetrated pursuant to an unconstitutional policy, custom, or practice of a governmental entity can never support a § 1983 claim. This summary of the law is incorrect. It is true that "[o]ne cannot infer a custom or practice from a single incident."*Estate of Moreland v. Dieter,*-F.3d-, Nos. 03-3734 & 03-3735, 395 F.3d 747, 2005 WL 77182 at *10 (7th Cir. Jan.14, 2005). However, a single violation of federal rights can trigger § 1983 under *Monell* if the violation was a "highly predictable consequence" of the governmental entity's failure to act and the plaintiff shows that an unconstitutional policy, custom, or practice existed at the time the plaintiff's rights were violated. *See id.; see also Arlotta v. Bradley Center,* 349 F.3d 517 (7th Cir.2003). Thus, the fact that Spencer's § 1983 claim is based on his arrest as opposed to a series of arrests of similarly situated individuals does not automatically doom his § 1983 claim against the Village of Wheeling.

3. Rehabilitation Act Claims Against All Defendants

***5** The Rehabilitation Act prohibits federal grant recipients from discriminating against otherwise qualified handicapped individuals solely because of their disability. 29 U.S.C. § 794(a). To state a claim under the Rehabilitation Act, the plaintiff must allege that: (1) he is a handicapped individual under the Act; (2) he is otherwise qualified for the benefit sought; (3) he was discriminated against solely by reason of his handicap; and (4) the program or activity in question receives federal financial assistance.*Grzan v. Charter Hosp. of Northwest Indiana,* 104 F.3d 116, 199 (7th Cir.1997).

Spencer alleges that the Village of Wheeling's police department failed to take appropriate measures to ensure that deaf and hard of hearing persons can communicate effectively with its personnel. He also alleges that the Village of Wheeling's police department receives federal funds "to effectuate [its] program or activity of enforcing the laws for the Village of Wheeling."He thus concludes that the individual defendants as well as the Village of Wheeling are liable under the Rehabilitation Act.

In response, the defendants argue that Spencer's Rehabilitation Act claims against the individual defendants are fatally flawed because there is no individual liability under the Act. This is correct, so the Rehabilitation Act claims against the individual defendants are dismissed with prejudice. *See EEOC v. AIC Security Investigations, Ltd.,* 55 F.3d 1276, 1279-82 (7th Cir.1995).

The defendants also contend that Spencer's Rehabilitation Act claims against the Village of Wheeling must be dismissed because the complaint does not allege that the events alleged in the complaint were related to a specific program sponsored by the Village of Wheeling and paid for at least in part with federal funds. The Rehabilitation Act, however, does not impose a heightened pleading standard upon plaintiffs. *See Chisolm v. Foothill Capital Corp.,* 940 F.Supp. 1273, 1280 (N.D.Ill.1996).

Moreover, at the pleading stage, a plaintiff will seldom be able to specifically allege the intricacies of the defendants' use of federal assistance. *See Byers v. Rockford Mass Transit Dist.,* 635 F.Supp. 1387, 1390 (N.D.Ill.1986). Finally, at the motion to dismiss stage, the type of detailed allegations suggested by the defendants are simply unnecessary. See *In Simpson v. Reynolds Metals Co.,* 629 F.2d 1226, 1234 n. 13 (7th Cir.1980) ("an allegation that the defendants received federal financial assistance [is] probably sufficient to apprise the defendants of the grounds of his [Rehabilitation Act] claim"); *Treadwell v. St. Joseph High School,* No. 98 C 4906, 1999 WL 753929 at *4 (N.D.Ill. Sep.15, 1999) (denying motion to dismiss where the plaintiff alleged that the defendant is a recipient of federal financial assistance); *Peterson v. Holy Cross Hosp.,* No. 86 C 9000, 1987 WL 9565 at *2 (N.D.Ill. Apr.14, 1987) (since the court must draw all reasonable inferences in the plaintiff's favor at the motion to dismiss stage, denial of the defendants' motion to dismiss was proper since it was possible

that the federal assistance received by the defendants had a sufficient relationship to the alleged discrimination); *Byers v. Rockford Mass Transit Dist.,* 635 F.Supp. at 1390 (the nexus between the use of federal funds and the discrimination alleged by a plaintiff "must be decided case by case based on the underlying facts surrounding the federal funding.... Stated another way, the issue of program specificity cannot be properly analyzed in the abstract, but instead requires a concrete set of facts.... As long as some federal funding is alleged, then, the program specificity issue is more properly the subject of a summary judgment motion") (internal citations omitted); *Lynn v. City of Chicago,* No. 86 C 2207, 1986 WL 8033 at *6 (N.D.Ill. Jul.15, 1986) (denying motion to dismiss where the plaintiff alleged that Chicago's police department discriminated against him and received federal funds because the court could not determine whether the City's receipt of federal funds in conjunction with the operation of its Police Department was a "program" under the Rehabilitation Act at the motion to dismiss stage). Accordingly, the Rehabilitation Act claims against the Village of Wheeling survive the motion to dismiss.

B. Motion to Strike

***6** Finally, the defendants ask the court to strike what they characterize as ambiguous language regarding punitive damages. They also contend that many of the allegations in the complaint should be stricken because they are "more fitting of a pulp fiction novel than a federal complaint," prejudice the defendants, and have little bearing on the case.

1. Punitive Damages

Municipalities are immune from punitive damages imposed under the civil rights laws. *City of Newport v. Fact Concerns, Inc.,* 453 U.S. 247, 271, 101 S.Ct. 2748, 69 L.Ed.2d 616 (1981); *Bell v. City of Milwaukee,* 746 F.2d 1205, 1270 (7th Cir.1994) (the punitive damages rule of *City of Newport* applies to § 1983 and § 1981 actions). Moreover, Illinois has reaffirmed immunity for its local governments in the Illinois Local Government and Governmental Employee Tort Immunity Act, 745 ILCS § 10/2-102. *Agnew v. Board of Educ. of City of Chicago,* No. 97 C 5993, 1998 WL 386155 at *6 (N.D.Ill. Jul.07, 1998). Thus, the Village of Wheeling is immune from any punitive damages award, so any request for such damages is stricken with prejudice.

2. Rule 12(f) Motion to Strike

A court may strike "any insufficient defense or any redundant, immaterial, impertinent or scandalous matter."Fed.R.Civ.P. 12(f). The defendants point to allegations such as Spencer's claim that he was "peacefully ensconced" in his trailer before his arrest, the description of Spencer's ex-girlfriend's expression as "smug," and Spencer's claim that the officers who arrested him were "sarcastic," "cavalier," and "dismissive of [his] obvious distress." According to the defendants, these allegations should be stricken because they are subjective, hyperbolic, have little bearing on the case, and are prejudicial.

Motions to strike under Rule 12(f) are disfavored and usually denied.*Spearman Indus., Inc. v. St. Paul Fire & Marine Ins. Co.,* 109 F.Supp.2d 905, 907 (N.D.Ill.2000). To prevail on a Rule 12(f) motion to strike, the defendants must demonstrate that the allegations at issue do not bear on the subject matter of the litigation and will prejudice them. *See, e.g., NOW, Inc. v. Scheidler,* 897 F.Supp. 1047, 1087 n. 28 (N.D.Ill.1995) ("[t]o strike portions of a complaint, the allegations being challenged must be so unrelated to plaintiff's claims as to be void of merit and unworthy of any consideration" and "must be prejudicial to the movant."(internal citations omitted).

It is true that the entire complaint is unusually detailed given the notice pleading standard used in federal court. *See*Fed.R.Civ.P. 8(a)(2) (a complaint should be a short and plain statement of the claim showing that the pleader is entitled to relief). Indeed, it reads more like a plaintiff's deposition taken in a § 1983 excessive force case than a federal court complaint. Nevertheless, the allegations in Spencer's complaint describe his view of the events surrounding his arrest. The fact that this view is unflattering to the defendants and is extremely detailed is not a valid reason to require Spencer to shorten his complaint as allegations in a complaint cannot be stricken merely because a defendant disagrees with them. *See Manuel v. Lucenti,* No. 04 C 2531, 2004 WL 2608355 at *2-3 (N.D. Ill. Nov 16, 2004). Accordingly, the defendants' motion to strike pursuant to Rule 12(f) is denied.

III. Conclusion

***7** For the above reasons, the defendants' motion to dismiss and strike is granted in part and denied in part. Specifically, Spencer's § 1983 claims against the Village of Wheeling are dismissed without prejudice, his Rehabilitation Act claims against the individual defendants are dismissed with prejudice, and his Rehabilitation Act claims against the Village of Wheeling survive the motion to dismiss. In addition, the defendants' motion to strike Spencer's request for punitive damages from the Village of Wheeling is granted, but the motion to strike the allegations in Spencer's complaint pursuant to Rule 12(f) is denied.

Spencer may file a second amended complaint by March 11, 2005, consistent with counsel's Rule 11 obligations and this order.

N.D.Ill.,2005.
Spencer v. Dawson
Not Reported in F.Supp.2d, 2005 WL 643331 (N.D.Ill.)

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APPENDIX 2

HExtra Equipamentos E Exportacao Ltda. v. Case Corp.
N.D.Ill.,2005.
Only the Westlaw citation is currently available.
United States District Court,N.D. Illinois, Eastern Division.
EXTRA EQUIPAMENTOS E EXPORTACAO LTDA. and Persio D. Briante, Plaintiffs,
v.
CASE CORPORATION, Defendant.
No. 01 C 8591.

Jan. 20, 2005.

Christopher Todd Sheean, Kelley, Drye & Warren, Chicago, IL, for Plaintiffs.
Brian Douglas Sieve, James C. Joslin, Jeffrey Richard Miller, Maria A. Meginnes, Kirkland & Ellis LLP, Chicago, IL, for Defendant.

MEMORANDUM AND ORDER

MANNING, J.
***1** Plaintiffs Extra Equipamentos E Exportacao Ltda. and Persio D. Briante (collectively, "Extra") filed the instant diversity action against Defendant Case Corporation ("Case") alleging fraudulent misrepresentation, negligent misrepresentation, and promissory fraud in connection with an agreement Extra entered into with Case Brasil & Cia ("Case Brasil"), Case's Brazilian subsidiary, which is not named as a defendant in this action.

The current matter is before the Court on Case's motion to dismiss Extra's Amended Complaint ("the Complaint"), pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), 12(b)(7), and 19, as well as on the grounds of forum non conveniens.[FN1] In the alternative, Case seeks to strike certain paragraphs in the Complaint under Rule 12(f). For the reasons that follow, the Court: (1) DENIES the motion to dismiss with respect to the fraud claims but GRANTS it as to the negligent misrepresentation claim; and (2) DENIES the motion to strike.

FN1. This motion comes before this Court on remand from the Seventh Circuit. In a prior opinion (2002 WL 1888540), this Court dismissed this case on the grounds that Extra failed to join an indispensable party (Case Brasil). The Court, however, did not discuss the other grounds on which Case moved to dismiss. On March 15, 2004, the Seventh Circuit, in *Extra v. Case,* 361 F.3d 359 (7th Cir.2004), vacated and remanded this dismissal order. The Court will now address the motion to dismiss consistent with the dictates of the Seventh Circuit and on the other grounds set forth in Case's motion.

BACKGROUND [FN2]

FN2. The facts in the background section are drawn from the Complaint. Although this Court discussed the facts in its prior opinion, it will again set forth the relevant facts as they relate to the issues presently before the Court.

The Parties

Extra is a Brazilian corporation which sells heavy farm and construction equipment in Brazil. At the time of the allegations in the Complaint, Extra was the leading distributor of Case products in Brazil. Briante, a citizen of Brazil, is the chief officer of Extra. Case, a Delaware corporation headquartered in Wisconsin, manufactures agricultural and construction machinery. Case Brasil is a Brazilian subsidiary of Case, whose principal business is the sale of Case equipment in Brazil.[FN3]

FN3. Case Brasil is a "100% subsidiary" of Case. *Extra v. Case,* 361 F.3d 359, 364 (7th Cir.2004).

Extra's Distributorship in Brasil

Since 1992, Extra has sold Case construction and farm equipment pursuant to distribution agreements between Extra and Case Brasil. Extra contends that although it was the largest distributor of Case equipment in Latin America, senior executives at

Case Brasil were improperly debiting Extra's account with Case Brasil to inflate Case Brasil's revenues and line their own pockets. According to Extra, Case Brasil was approving high risk loans for farm equipment on behalf of Extra. When the customers defaulted, Case Brasil then debited the bad loans against Extra's account with Case Brasil, thereby cheating Extra out of revenue which it had rightfully earned and forcing Extra to absorb the losses for loans which it had no part in procuring.

As a result of these improper charge backs, in July of 1999, Extra brought suit against Case Brasil in Brazil ("the Brazilian Action"), seeking: (a) payment of all commissions owed to Extra; (b) reversal of the illegitimate debits transferred to Extra's current account; and (c) payment for repairs and parts provided by Extra to Case Brasil's "commission" customers.

Around the time of the Brazilian Action, Case began investigating suspected improper activities of executives at Case Brazil and was involved in negotiations for a merger with another company. The executives, who were being investigated, were the same individuals who allegedly forced Extra to accept the improper charge backs. According to Extra, Case knew that the top managers at Case Brasil were acting in an improper and fraudulent manner but could not find proof to sustain their suspicious. Extra also contends that Case was concerned that if the suspected improper activities at Case Brasil became public, its anticipated merger would be put at risk. Case was also troubled that Extra had filed objections to its pending merger with the Brazilian government.

The Waukegan Agreement

***2** In October of 1999, Case's in-house counsel and counsel for Extra began negotiations to resolve the Brazilian Action and to assist Case with its merger and its internal investigation of Case Brasil. Shortly after an initial meeting in Brazil, Extra and Case agreed that Mr. Briante (Extra's president) and the head of Case's Latin American operations (Mr. James Sharman) would meet in Waukegan, Illinois, on October 19, 1999, to sign an agreement resolving the above issues (the "Agreement" or "Waukegan Agreement").

Under the terms of the Waukegan Agreement, which was drafted the night before by Case's in-house counsel without consulting anyone at Case Brasil, Case Brasil agreed to: (1) continue Extra's distributorship on terms at least as favorable as those offered other distributors; (2) resolve the alleged improper charge backs by capping Extra's liability at a set amount; and (3) present Extra with a "controlling Portugese version" of the Agreement. In exchange for these concessions, Extra agreed to: (1) supply Case with information it needed to prove the wrong-doing by management at Case Brasil; and (2) not interfere with Case's anticipated merger.

Although not officers at Case Brasil, Mr. Sharman, who executed the Agreement on behalf of Case Brasil, and Case's in-house counsel allegedly assured Extra that Mr. Sharman had the authority to bind Case Brasil and that Case Brasil would abide by the terms of the Agreement. Indeed, the Agreement states that it was "entered into by and between Case Brasil & Cia and Equipamentos Exportacao Ltda" and defines the term "Case" to include "Case Brasil & Cia, Case Corporation, and their past, present, and future: subsidiaries, divisions, parent corporation, predecessors...." Also set forth in the Agreement was a clause which stated: *"Representation and Warranty As to Authority.*Each [p]erson signing this document represents and warrants that he or she has full authority to enter into [this Agreement]."

Based on Case's representations and the terms of the Agreement, Extra immediately supplied Case with information detailing the wrongful conduct of the Case Brasil officers. With this evidence, Case was able to "fire" the wrong-doers at Case Brasil and take back control of its subsidiary. Also, with its internal problems resolved and without any objection from Extra, Case was able to successfully complete its merger.

Despite having fully complied with its obligations under the Agreement, Extra alleges that Case Brasil, although a 100% subsidiary of Case, has completely ignored its obligations under the Agreement. Case Brasil contends that the Waukegan Agreement is not binding because Mr. Sharman was not a Case Brasil officer nor was he authorized to bind Case Brasil. Case, despite representations to the contrary, has done nothing to ensure that Case Brasil follow the terms of the Agreement. In fact, Case Brasil has

sought to terminate Extra's distributorship. Adding insult to injury, Case now allegedly contends that the Agreement was negotiated between Extra and Case Brasil, and therefore, this dispute is solely between them.

***3** As a result of the above actions, in November of 2001, Extra filed its initial complaint against Case, alleging breach of contract and fraud. Extra alleged that Case breached the Agreement by its failure to have Case Brasil abide by its obligations thereunder, such as fixing the improper charge backs and retaining Extra as a distributor.

In response to the original complaint, Case filed its initial motion to dismiss for failure to join an indispensable party (Case Brasil) and on grounds of forum non conveniens. After interpreting the language of the Agreement, this Court held in an August 13, 2002 Memorandum and Order ("August Order") that Case Brasil was a party to the Agreement and therefore was a necessary and indispensable party under Rule 19. This determination was based in part on the language of the Agreement, which defines "Case" to include Case Brasil; states the signing parties are identified in the contract as "EXTRA EQUIPAMENTOS EXPORTACAO LTD." and "CASE BRASIL & CIA"; and contains the subheading "[t]his Release ... is entered into by and between Case Brasil & Cia and Extra Equipamentos Exportacao Ltda."Accordingly, the Court granted the motion to dismiss the initial complaint.

The Court, however, withdrew its August Order, on November 22, 2002, because Extra did not respond to the initial motion to dismiss before the Court issued its dismissal order. Case filed its initial motion to dismiss on January 7, 2002. Instead of appearing before this Court to seek an extension of the briefing schedule on the initial motion to dismiss, however, Extra simply sought leave from the magistrate judge to take limited jurisdictional discovery without notifying this Court. Consequently, because Extra did not respond to the initial motion to dismiss, this Court ruled on the motion. When withdrawing the August Order dismissing this action, this Court set a briefing schedule and granted Extra leave to amend its complaint.

In an attempt to plead around this Court's August Order finding that Case Brasil was a party to the Agreement and therefore an indispensable party, Extra does not allege breach of contract in its Amended Complaint. Instead, Extra has pled only tort claims solely against Case. The Amended Complaint alleges fraudulent misrepresentation (Count I), negligent misrepresentation (Count II), and promissory fraud (Count III). Extra contends that Case "perpetrated a fraudulent scheme" and "made utterly reckless misrepresentations" to Extra to induce Extra to enter into the Agreement. Case allegedly "manipulated the corporate distinction between itself and Case Brasil" and misrepresented that Mr. Sharman had authority to sign the agreement on behalf of Case Brasil, when he in fact did not. Extra alleges that Case knew that Case Brasil, who was to take action under the Agreement, would not follow or comply with the terms of the Agreement and that Mr. Sharman did not have the authority to bind Case Brasil.

***4** In response to the Amended Complaint, Case filed the instant motion to dismiss.

ANALYSIS

Case contends that dismissal is proper on the grounds that: (I) Extra failed to join an indispensable party (Case Brasil); (II) Brazil is the proper location for this action (forum non conveniens); and (III) the Complaint does not sufficiently allege a cause of action. In the event that dismissal is not granted, Case seeks to strike portions of the Complaint. The Court will address each of these contentions in turn.

I. Failure to Join an Indispensable Party [FN4]

> FN4. In ruling on a motion to dismiss for failure to join an indispensable party, the court must accept the allegations of the complaint as true. *Davis Companies v. Emerald Casino, Inc.*, 268 F.3d 477, 479 (7th Cir.2001); *Pasco Int'l (London) Ltd. v. Stenograph Corp.*, 637 F.2d 496, 499 (7th Cir.1980). The court may, however, look outside of the pleadings and consider extrinsic evidence. *Davis*, 268 F.3d at 480;*English v. Cowell*, 10 F.3d 434, 437 (7th Cir.1993); *Capitol Leasing Co. v. Fed. Dep. Ins. Corp.*, 999 F.2d 188, 191 (7th Cir.1993).

In an opinion dated June 6, 2003 (2002 WL 1888540), this Court found that Case Brasil was a necessary and indispensable party under Rule 19, and therefore, dismissed this action for failure to join an indispensable party. On appeal, the Seventh Circuit vacated and remanded this dismissal "consistent with the guidance provided by this opinion."In so holding, the court held that in analyzing "indispensability," the district court should have taken into account the fact that Case Brasil was a "100 percent subsidiary" of Case. According to the Seventh Circuit, it is extremely unlikely that Case Brasil would be prejudiced if not a party to this action because Case would fully protect Case Brasil's interests as it is its wholly owned subsidiary.[FN5]Therefore, the court noted that one of the Rule 19(b) factors (prejudice to the absent party) could likely not be met. In reaching this conclusion, the court stated that "we have great difficulty seeing how a 100 percent subsidiary could *ever* be an indispensable party."(Emphasis in original.)

> FN5.Rule 19(b) provides four factors to be considered in determining whether a party is "indispensable." These factors are: "(1) the extent to which a judgment entered in the absence of a party will be prejudicial to those currently before the court; (2) the extent to which such prejudice can be lessened or avoided by reshaping the judgment; (3) whether a judgment entered in a party's absence will be adequate; and (4) whether the plaintiff will have an adequate remedy if the action is dismissed."*Moore v. Ashland Oil, Inc.,* 901 F.2d 1445, 1447 (7th Cir.1990).

Following the above instructions, this Court has not found, nor has Case cited, any authority or facts supporting the conclusion that Case Brasil (as a 100 percent owned subsidiary) would or could be overtly prejudiced by not being a party to this action. Accordingly, this Court, in the exercise of its discretion, now finds a judgment in this case would not prejudice Case Brasil to such an extent as to render it an indispensable party.

II. Forum Non Conveniens [FN6]

> FN6. As in the motion to dismiss for failure to join indispensable parties, in ruling on a forum non conveniens motion the Court may look at facts outside the four corners of the complaint. *See*Hidrovia v. Great Lakes Dredge & Dock Corp., 2003 WL 2004411, at *3 (N.D.Ill. April 28, 2003).

The Court next turns to whether this action should be dismissed under the forum non conveniens doctrine. Under this doctrine, a court may dismiss an action "over which it would normally have jurisdiction if it best serves the convenience of the parties and the ends of justice."*Kamel v. Hill-Rom Co.,* 108 F.3d 799, 802 (7th Cir.1997). Dismissal, however, is only appropriate if the chosen forum "would result in vexation and oppression to the defendant which would far outweigh the plaintiff's convenience."*Id.*

In ruling on a forum non conveniens motion, courts must: (1) assess whether there is an adequate alternative forum; and (2) balance the private and public interests factors.[FN7]*Id.* at 802-03.Private factors include: the plaintiff's choice of forum; [FN8] location and access to evidence and witnesses; convenience to the parties and the witnesses; and any other "practical problems that make trial of a case easy, efficient and economical."*Id.* at 803.The public interest factors consist of:

> FN7. An adequate alternative forum exists if "all parties are amenable to process" and "the parties will not be deprived of all remedies or treated unfairly."*Kamel,* 108 F.3d at 802. Here, the parties do not contest that Brazil is an adequate alternative forum. Moreover, in the appeal of the Rule 19 motion, the Seventh Circuit held that "Case is suable [in Brasil]" because "it moved to have the case transferred [there], and we take this to be binding consent to be sued there."*Extra v. Case,* 361 F.3d 359, 361 (7th Cir.2004).
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> FN8. Although the plaintiff's choice of forum is usually given great deference, where the plaintiff is foreign corporation, its choice is accorded little deference. *See*Piper Aircraft Co. v. Reyno, 454 U.S. 235, 266, 102 S.Ct. 252, 70 L.Ed.2d 419 (1981).

***5** the administrative difficulties stemming from

court congestion; the local interest in having localized disputes decided at home; the interest in having the trial of a diversity case in a forum that is at home with the law that must govern the action; the avoidance of unnecessary problems in conflicts of law or in the application of foreign law; and the unfairness of burdening citizens in an unrelated forum with jury duty.
Id.

The defendant bears the burden of persuasion of the private and public factors. *Gupta v. Austrian Airlines,* 211 F.Supp.2d 1078, 1087 (N.D.Ill.2002). To meet this burden, the movant must "provide enough information to enable the court to balance the parties' interests."*Id.* Exactly how much information must be provided is left to the discretion of the district court and should be decided on a case by case basis. *See, e.g.,Hidrovia.,* 2003 WL 2004411, at *3. Generally, the defendant does not need to provide detailed affidavits "identifying the witnesses [it] would call and the testimony these witnesses would provide if the trial were held in an alternative forum."*Piper,* 454 U.S. at 258. The defendant, however, must at least identify the specific witnesses who will not be able to testify in the chosen forum and the documents vital to the action which are located in the alternative forum. *SeeGupta,* 211 F.Supp.2d at 1087;*Hidrovia.,* 2003 WL 2004411, at *3. The defendant must present sufficient information for the court to "have a basis upon which to scrutinize the substance of the dispute between the parties to evaluate what proof is required, and determine whether the pieces of evidence cited by the parties are crucial, or even relevant, to the plaintiff's cause of action and to any potential defenses to the action."*In re Bridgestone, Inc.,* 305 F.Supp.2d 927, 933 (S.D.Ind.2004). In other words, the court must look at the access to proof factor in context of the "gravamen" of the claim and "where the dispute is centered." *SeeHidrovia.,* 2003 WL 2004411, at *3. Where the defendant "fail[s] to identify any necessary document, witness, or third-party defendant located in [the foreign country], which would be unavailable for trial" in the chosen forum, courts generally find that the private interest factor does not favor dismissal. *SeeIn re Bridgestone, Inc.,* 305 F.Supp.2d at 933.

Here, after carefully examining the parties' submissions and the Complaint, this Court, in exercise of its discretion, finds that neither the private nor public factors support dismissal of this case under the forum non conveniens doctrine. The two factors pertinent to this Court's decision (which are the two factors Case raises in its motion) are whether the key witnesses and documents needed to resolve this action are located in Brazil and whether this Court will have to apply Brazilian law.

Case has not set forth any specific names of witnesses or documents pertinent to the germane issues in this case that are located in Brazil. Instead, Case states generally that the "relevant documents" and Case Brasil employees with knowledge of Case Brasil's non-compliance with the terms of the Waukegan Agreement are located in Brazil. Thus, according to Case, the access to witnesses and documents factor favors dismissal.

***6** Case's contention is misguided. It is undoubtedly true that some documents and witnesses supporting Case Brasil's failure to perform under the Agreement are located in Brasil. Extra, however, does not seek redress for Case Brasil's breach of the Waukegan Agreement. Instead, Extra has pled tort claims-negligent and fraudulent misrepresentation and promissory fraud-solely against Case. Extra contends that Case "perpetrated a fraudulent scheme" and "made utterly reckless misrepresentations" to induce Extra to enter into the Agreement. Specifically, Case allegedly "manipulated the corporate distinction between itself and Case Brasil" and misrepresented Mr. Sharman's authority to sign the agreement on behalf of Case Brasil. These misrepresentations were made by Case employees from their headquarters in Racine, Wisconsin and/or in Waukegan, Illinois. While testimony of Case Brasil employees and documents located in Brazil could be relevant in this case, such evidence would only shed light on tangential issues-*e.g.,* whether and why Case Brasil refused to honor the Waukegan Agreement. This evidence, however, is not necessary for this Court to determine if case made misstatements or used fraud to induce Extra to enter into the Waukegan Agreement.

Likewise, Case's contention that Brazilian law governs this action is incorrect. Federal courts sitting in diversity apply the choice of law doctrine of the state in which the court sits (in this case Illinois).*ECHO, Inc. v. Whitson, Co.,* 52 F.3d 702, 706 (7th Cir.1995). In tort cases, Illinois uses the

"most significant relationship" test adopted from the Restatement (Second) of the Conflict of Laws.[FN9] *Reid v. Norfolk & Western Ry. Co.*, 157 F.3d 1106, 1110 (7th Cir.1998). In applying the most significant relationship test, courts consider: (1) the place of the injury; (2) the location of the tortious conduct; (3) the domicile of the parties; and (4) the center of the parties' relationship. *Fredrick v. Simmons Airlines, Inc.*, 144 F.3d 500, 503-04 (7th Cir.1998).

> FN9. The choice of law clause in the Waukegan Agreement (requiring the Agreement be interpreted under Brazilian law) is not dispositive because Extra alleges claims for tort not breach of contract. *See* *First Nat'l Bank of Boston v. Heuer*, 702 F.Supp. 173, 175-76 (N.D.Ill.1988) (applying the most significant relationship test in a tort action for fraudulent misrepresentation in the context of a contract, the court disregarded the contract's choice of law provision because the "action [was] in tort, not contract").

The above factors are not applied equally or consistently in all tort actions. For example, in *First National Bank of Boston v. Heuer*, 702 F.Supp. 173, 174 (N.D.Ill.1988), the plaintiff, a Massachusetts company, brought an action for fraudulent misrepresentation against a company located in Illinois. The plaintiff alleged that the defendant made misrepresentations in securing a line of credit. *Id.* Applying the most significant relationship test, the court held that "in cases of fraud and or misrepresentation, unlike personal injury actions, the place of loss is less important than the place the defendant allegedly made the misrepresentations."*Id.* at 175-76.The court thus found that Illinois law applied "because the alleged misrepresentations were made in Illinois" by an Illinois resident. *Id.* at 176.*See also* *Snyder v. Fahim*, 1987 WL 14022, at *3 n. 1 (N.D.Ill. July 16, 1987) (applying the most significant contacts test in a fraudulent misrepresentation case, the court held that Missouri law applied because the defendant's "fraudulent conduct took place in Missouri"); *Gates Rubber Co. v. USM Corp.*, 351 F.Supp. 329, 338-39 (N.D.Ill.1972) (applying New York law because the fraudulent misrepresentations were made there), *rev'd on other grounds*, 508 F.2d 603 (7th Cir.1975).

***7** Here, while Extra's injuries and its relationship with Case Brasil are centered in Brazil, the misrepresentations which are at the heart of the tort claims in the Complaint were made by Case to Extra in Illinois. Case allegedly induced Extra to come to Illinois and sign the Waukegan Agreement based on its false representations that it "had full authority to bind Case Brasil."The Agreement itself, which was drafted by Case's in-house counsel in Illinois or Wisconsin, stated that it was between Case Brasil and Extra and warranted that the signer for Case (Mr. Sharman) had authority to bind Case Brasil. According to Extra, these statements were all false because Case knew at the time of making these statements that Mr. Sharman had no such authority and that Case Brasil would not abide by the terms of the Agreement. This Court thus finds that Illinois law applies because all (or at least the majority) of the alleged misrepresentations were made in Illinois.

Accordingly, this Court denies the motion to dismiss on forum non conveniens grounds. Also relevant to this Court's decision is the fact that Extra has "chosen a forum which is [in Case's] own back yard," and thus Case can hardly complain about this venue being inconvenient. *See* *Gassner v. Stotler and Co.*, 671 F.Supp. 1187, 1190-91 (N.D.Ill.1987) (denying forum non conveniens motion where plaintiffs, who were German citizens, sued an Illinois partnership in federal court in Chicago for fraudulent activity perpetrated by the defendant in Illinois).

III. 12(b)(6) Motion to Dismiss [FN10]

> FN10. In ruling on a motion to dismiss pursuant to Rule 12(b)(6), the court must assume the truth of all facts alleged in the pleadings, construing allegations liberally and viewing them in the light most favorable to the non-moving party. *See, e.g.,* *McMath v. City of Gary*, 976 F.2d 1026, 1031 (7th Cir.1992); *Gillman v. Burlington N. R.R. Co.*, 878 F.2d 1020, 1022 (7th Cir.1989). Dismissal is properly granted only if it is clear that no set of facts which the plaintiff could prove consistent with the pleadings would entitle the plaintiff to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Kunik v. Racine County, Wis.*, 946 F.2d 1574, 1579 (7th Cir.1991)

> (*citing* *Hishon v. King & Spalding*, 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984)). The court will accept all well-pled factual allegations in the complaint as true. *Miree v. DeKalb County*, 433 U.S. 25, 27 n. 2, 97 S.Ct. 2490, 53 L.Ed.2d 557 (1977). In addition, the court will construe the complaint liberally and will view the allegations in the light most favorable to the non-moving party. *Craigs, Inc. v. General Electric Capital Corp.*, 12 F.3d 686, 688 (7th Cir.1993). However, the court is neither bound by the plaintiff's legal characterization of the facts, nor required to ignore facts set forth in the complaint that undermine the plaintiff's claims. *Scott v. O'Grady*, 975 F.2d 366, 368 (7th Cir.1992).
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> > Here, the parties have cited to affidavits and other documents attached to their submissions. While this Court considered this evidence in ruling on the above motions, it will not consider it when deciding the Rule 12(b)(6) motion. Moreover, at this point in time, particularly given the fact that only limited jurisdiction discovery had been taken at the time this motion was filed, the Court will not convert the motion into a motion for summary judgment.

Case also moves to dismiss this action under Rule 12(b)(6) on the grounds that Extra has failed to plead a claim for misrepresentation (both fraudulent and negligent) or promissory fraud and that Extra has failed to plead fraud with sufficient particularity as required by Rule 9(b).[FN11]

> FN11. As explained above, this Court will apply Illinois substantive law to Extra's claims.

A. Misrepresentation Claims

To plead a claim for fraudulent misrepresentation under Illinois law, a plaintiff must allege: (1) the defendant made a false statement of material fact; (2) the defendant knew the statement to be false; (3) the defendant intended to induce the plaintiff to act with the false statement; (4) the plaintiff relied upon the truth of the false statement; and (5) the plaintiff suffered damages as a result of relying on the false statement. *W.W. Vincent & Co. v. First Colony Life Ins. Co.*, 351 Ill.App.3d 752, 286 Ill.Dec. 734, 814 N.E.2d 960, 969 (Ill.App.Ct.2004). A claim for negligent misrepresentation requires the same, except that: (1) instead of alleging that the defendant knew the statement was false, the plaintiff need only allege that the defendant was careless or negligent in ascertaining the veracity of the statement; and (2) the plaintiff must also allege that the party making the statement was "under a duty to communicate accurate information." *Fox Assocs., Inc. v. Robert Half Int'l, Inc.*, 334 Ill.App.3d 90, 267 Ill.Dec. 800, 777 N.E.2d 603, 606 (Ill.App.Ct.2002).

Here, Case contends that Extra has failed to plead an actionable claim for misrepresentation because: (1) Case Brasil ratified the Agreement, and thus, no false statement was made; and (2) Extra has not sufficiently alleged that it relied on a misrepresentation or that a misrepresentation caused it to suffer damages. Case also contends that the negligent misrepresentation claim fails because Extra has not alleged that the Case employees, who allegedly made the false statement, were under a duty to communicate accurate information. The Court will address these three contentions in turn.

***8** *First,* Case contends that Extra has failed to allege the existence of a false statement because even if it signed the Waukegan Agreement without the authority to bind Case Brasil, Case Brasil ratified the Agreement two weeks afterwards when it signed a power of attorney ("the Power of Attorney") appointing Mr. Sharman its "attorney-in-fact." There are a number of problems with this contention. For one, the Power of Attorney is not mentioned nor attached to the Complaint, and therefore, in ruling on a Rule 12(b)(6) motion, this Court should not even take it into consideration. Moreover, even if this Court were to convert this motion into a motion for summary judgment, the parties have submitted conflicting affidavits as to whether the Power of Attorney is even valid under Brazilian law. Thus, at this time, dismissal on the grounds that Case Brasil ratified the Waukegan Agreement by executing the Power of Attorney is not appropriate.[FN12]

> FN12. The Court also notes that even if Case had authority to bind Case Brasil pursuant to the Power of Attorney, dismissal

would not be proper because Extra alleges other misrepresentations, such as that Case knew that Case Brasil would not abide by the terms of the Agreement but nevertheless induced Extra to execute the Agreement.

Second, this Court finds that Extra has sufficiently alleged causation and reliance.[FN13]As set forth in more detail above, Extra alleges that Case "perpetrated a fraudulent scheme" to induce Extra to enter the Waukegan Agreement. As part of this scheme, Case "manipulated the corporate distinction between itself and Case Brasil" and misrepresented that Mr. Sharman had authority to sign the agreement on behalf of Case Brasil. "In reliance on [these and other] representations" Extra executed the Agreement and provided Case information regarding the wrong-doing by Case Brasil officers while keeping this information quiet so as not to upset Case's proposed merger. Extra further alleges that its reliance was "reasonable ... as Mr. Sharman was a senior Case executive" who headed its Latin American operations, which included Case Brasil. As a result of its reliance, Extra alleges that it suffered damages including losing its Case distributorship and not resolving the illegal charge back dispute. Accordingly, this Court finds that Extra has sufficiently alleged reliance and causation.

FN13. The elements of causation and reliance for negligent misrepresentation are the same as for other torts-the plaintiff must allege it reasonably relied on the false statement and "but for" the false statement the plaintiff would not have incurred the harm alleged in the complaint. *See*Continental Assurance Co. v. Dean Witter Reynolds, Inc., 1993 WL 101448, at *2 (N.D.Ill. April 5, 1993).

Third, Case also contends that Extra has failed to plead negligent misrepresentation because it has not sufficiently alleged that Case had a duty to supply accurate information to Extra. Extra does allege that "Case had a duty to communicate accurate information to Extra and Mr. Briante with respect to Case's authority to enter into the Waukegan Agreement."(Am. Complt. at ¶ 94.) While federal notice pleading it very lenient, this is a legal conclusion. Thus, the Court finds that this broad allegation is insufficient to plead a duty for a claim of negligent misrepresentation.

Realizing this defect, Extra contends that it has properly pled the existence of a duty by alleging that Case's senior in-house corporate counsel (Mr. Brian Cahill) had a duty to provide accurate information to Extra with regard to Case's authority to bind Case Brasil to the Agreement. The Court will thus examine when an attorney has a duty to provide accurate information to a third-party non-client.

***9** Illinois law generally does not impose a duty to provide accurate information unless the defendant is in the "business of providing information for the guidance of others in business dealings."*Guar. Residential Lending Inc. v. Int'l Mortgage Center, Inc.,* 305 F.Supp.2d 846, 863 (N.D.Ill.2004). This exception is usually applied to "pure information" providers such as banks providing credit information to a potential lender, real estate agents, title companies, and stock brokers. *Fox Assocs., Inc.,* 267 Ill.Dec. 800, 777 N.E.2d at 607-08. In determining if such a duty exists, courts generally must make a "precise, case-specific inquiry." *Guar, Residential Lending Inc. v. Int'l Mortgage Center, Inc.,* 305 F.Supp.2d at 863. While "supplying information need not encompass" the parties' "entire" business dealings, it must have been "central to business transaction between the parties."*Fox Assocs., Inc.,* 267 Ill.Dec. 800, 777 N.E.2d at 607. The court thus must carefully examine "the nature of the information at issue and its relation to the kind of business being conducted" and what was the "ultimate" goal of the parties' business transaction. *Id.* at 608-09.

For a non-client to make a claim of negligent misrepresentation against an attorney, the non-client must allege more than the fact that the attorney supplied information to it to facilitate a transaction between the client and the non-client. *See*Astor Chauffeured Limousine Co. v. Runnfeld Investment Co., 1988 WL 101267, at *5-6 (N.D.Ill. Sept.1988) (rejecting a broad proposition that attorneys are in the business of supplying information and thus have a general duty to provide accurate information to non-clients). Instead, the court must closely examine the transaction between the client and the non-client and what role the attorney played in the deal. *Id.* For an attorney to have a duty to provide accurate information to a non-client, the non-client must allege that "the primary purpose and intent of the

attorney-client relationship itself was to benefit or influence the third party."*Greycas v. Proud,* 826 F.2d 1560, 1563-64 (7th Cir.1987).*See also**Wafra Leasing Co. v. Prime Capital Corp.,* 192 F.Supp.2d 852, 874 (N.D.Ill.2002); *Astor Chauffeured Limousine Co.,* 1988 WL 101267, at *5-6.

In cases where a duty was found to lie, the client retained the attorney for the limited purpose of supplying the non-client information to facilitate a particular business transaction. For example, in *Greycas,* 826 F.2d at 1562, the attorney was retained to assist in the completion of a loan. Pursuant to the loan agreement, the prospective borrower retained the attorney for the sole purpose of conducting a search for existing liens on the collateral. *Id.* The attorney, despite not conducting a lien search, sent a letter to the lender/non-client stating that there were no liens on the collateral. *Id.* After it turned out that there were existing liens, the non-client sued the attorney for negligent misrepresentation. *Id.* Affirming judgment against the attorney, the Seventh Circuit held that the attorney had a duty to supply the non-client with accurate information because the client retained the attorney for the sole purpose of supplying information to the non-client to facilitate the transaction between his client and the non-client. *Id.* at 1563-65.

***10** Similarly, in *Wafra Leasing Co.,* 192 F.Supp.2d at 858, 874, a non-client sued an attorney who prepared an opinion letter valuing assets which the non-client later purchased. In denying the attorney's motion to dismiss, the court noted that the non-client sufficiently pled negligent misrepresentation by alleging that the client retained and directed the attorney to draft the opinion letter, which was intended to benefit the non-client in the transaction with the non-client. *Id.*

In contrast to *Greycas* and *Wafra,* the court in *Astor Chauffeured Limousine Co.,* 1988 WL 101267, at *5-6, held that an attorney did not have a duty to supply accurate information to a non-client. The plaintiffs in *Astor* entered into an agreement to sell a business which was owned in part by the defendant attorney. *Id.* at *1-2.The plaintiffs alleged that the attorney "made several material misrepresentations and failed to disclose several material facts in [the] written agreement and during the course of their prior negotiations."*Id.* at *2. In granting summary judgment on the negligent misrepresentation claim against the attorney, the court held that he did not owe a duty to the non-client plaintiffs because his representation was not "intended to confer directly a benefit upon plaintiffs."*Id.* at *5. This decision was based in large part on the plaintiffs allegation that "the purpose" of the attorney's "representation was to induce [the] plaintiffs to purchase ... two companies that would soon be financial failures."*Id.*

Here, unlike *Greycas* and *Wafra,* Extra has not alleged that Mr. Cahill was retained to supply information to Extra for the purpose of facilitating the execution of the Waukegan Agreement. Instead, like the plaintiff in *Astor,* Extra alleges that the purpose of Mr. Cahill's representation was to draft the Agreement and to induce Extra to enter into the Agreement, which only provided illusory benefits to Extra. Moreover, as in-house counsel for Case, this Court fails to see how Extra could allege that Mr. Cahill was retained by Case solely to provide information to Extra. This Court has not found, nor has Extra cited, any authorities holding that an in-house counsel has a duty to supply accurate information to entities other than to its employer/client.

A close look at the facts alleged in the Complaint reveal that Mr. Cahill acted in a manner consistent with representing his client (Case), not that he was retained to supply information to Extra. Mr. Cahill first met with Extra on October 13, 1999, in Brazil to discuss why Extra had filed objections to Case's proposed merger and to attempt to get more information regarding the improper conduct by officers at Case Brasil. Extra informed Mr. Cahill that its "objections were filed to get Case's attention" so it could discuss the improper charge backs by Case Brasil. (Am. Complt. at ¶¶ 39-40, 48-50.) Shortly after returning to the United States, at the request of Extra, Mr. Cahill arranged a meeting in Waukegan, Illinois between himself, Mr. Sharman, Mr. Briante, and Extra's Brazilian attorney. To keep their meeting a secret-so as not to alert the Case Brasil officers suspected of the wrongdoing-Mr. Cahill arranged for the parties to meet in a conference room at an airport in Waukegan, Illinois. Extra alleges that the secrecy of the meeting was essential because Mr. Briante was afraid that the Case Brasil officers might have him killed if they learned that he was informing the home office of their wrongful conduct. The night before the

meeting, Mr. Cahill prepared a draft of the Agreement without consulting Case Brasil. (*Id.* ¶¶ 50-53.)

***11** At the start of the meeting, which took place in Illinois on October 19, 1999, either Mr. Cahill or Mr. Sharman immediately asked Mr. Briante to detail the improper conduct of the Case Brasil officers. In response, Mr. Briante stated that he would not divulge any information until Extra's concerns-the improper charge backs and continuation of its distributorship-were resolved. Later that day, after Mr. Cahill made the alleged misrepresentations, Extra executed the Agreement and then gave Case the desired information.

This Court thus holds that Extra has not alleged sufficient facts to plead that Mr. Cahill had a duty to supply it with accurate information and thus cannot plead negligent misrepresentation. To hold otherwise would result in all in-house attorneys being liable for negligent misrepresentation for making any incomplete or inaccurate statements when negotiating a contract on behalf of their employers. Such a result would contravene the long-standing policy under Illinois law to narrowly construe the "tort of negligent misrepresentation" to "preserve the sphere appropriately governed by contract law from intrusion by tort."*See*Continental Assurance Co. v. Dean Witter Reynolds, Inc., 1993 WL 101448, at *13 (N.D.Ill. April 5, 1993). Accordingly, this Court grants the motion to dismiss as to the negligent misrepresentation claim.

B. Promissory Fraud

To state a claim for promissory fraud under Illinois law, a plaintiff must allege that the defendant made a false promise or representation of future performance, "not intending to keep the promise but intending for another party to rely on it, and where the other party" in fact relied on the false promise to its detriment. *Bower v. Jones,* 978 F.2d 1004, 1011 (7th Cir.1992). "To survive the pleading stage," the plaintiff must also allege "specific, objective manifestations of fraudulent intent-a scheme or device" used to "accomplish the fraud." *Id.* at 1011-12.In determining if a plaintiff has sufficiently pled intent, courts examine whether the defendant had a motive and what benefits were bestowed on the defendant by not following through on its alleged promise. *Seeid.*When analyzing whether there was a scheme to defraud, courts look at whether the alleged "broken promise is embedded in a larger pattern of deceptions or enticements that reasonably induces reliance against which the law ought to provide a remedy."*AAR Int'l, Inc. v. Vacances Heliades S.A.,* 202 F.Supp.2d 788, 799 (N.D.Ill.2002) (finding a scheme to defraud adequately alleged where "defendants alleged a number of related broken promises").

Here, after carefully examining the Complaint, this Court finds that Extra has sufficiently pled fraudulent intent and the existence of a scheme to defraud. Extra alleges that in October of 1999, Case was facing a pending crisis as a result of illegal conduct by certain Case Brasil officers. Case was allegedly fearful that this illegal conduct would hurt Case's Latin American sales, result in litigation in Brazil, and derail on-going negotiations which Case was undertaking to merge with another company. Although Case had investigated the improprieties at Case Brasil, it was unable to procure sufficient evidence to adequately handle the situation. To resolve this problem, Case looked to Extra, which had the evidence that Case needed to fire the Case Brasil officers engaged in the illegal conduct.

***12** According to Extra, Case (by Sharman and Cahill) "perpetrated a fraudulent scheme" and "made utterly reckless misrepresentations" to Extra to induce Extra to come to Illinois to enter into the Waukegan Agreement, knowing that Case Brasil, who was to take action under the Agreement, would not follow or comply with the terms of the Agreement. As part of this scheme, Case allegedly: (1) "manipulated the corporate distinction between itself and Case Brasil" and (2) misrepresented Mr. Sharman's authority to sign the agreement on behalf of Case Brasil. Case also promised Extra that Case Brasil would, among other things, retain Extra as a distributor and resolve the improper charge back dispute. In return, Extra agreed to: (1) provide Case with information regarding fraudulent activities of executives at Case Brazil; (2) not contest the propose merger between Case and a third-party; and (3) limit its claims against Case Brasil regarding illegal charge backs.

Immediately after signing the Agreement, Extra provided Case with detailed proof of the improper

conduct of the Case Brasil officials. Armed with this information, Case then fired these employees. With the problems at Case Brasil resolved and with Extra not objecting, Case was then able to complete its merger. Despite having fulfilled its obligations under the Agreement, Extra alleges that Case Brasil has completely disavowed any duty to perform. According to Extra, contrary to statements made prior to the signing and in the Agreement, Mr. Sharman was not an officer of Case Brasil and had no authority to bind Case Brasil to the Agreement. After receiving the benefits under the Agreement, Case now allegedly asserts that this dispute is between Extra and Case Brasil.

Accordingly, this Court finds that Extra has sufficiently alleged fraudulent intent and a scheme to defraud and thus DENIES Case's 12(b)(6) motion to dismiss Extra's promissory fraud claim.

C. Rule 9(b) Pleading Requirements

Rule 9(b) provides that "the circumstances constituting fraud ... shall be stated with particularity."Fed.R.Civ.P. 9(b). Circumstances constituting fraud "include the identity of the person who made the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff."*General Elec. Capital v. Lease Resolution,* 128 F.3d 1074, 1078 (7th Cir.1997). In other words, Rule 9(b) requires a plaintiff to plead "the who, what, when, where and how" of the fraud. *DiLeo v. Ernst & Young,* 901 F.2d 624, 627 (7th Cir.1990). The purpose underlying Rule 9(b)'s particularity requirement is to: (1) protect the defendant's reputation; (2) minimize "strike suits and fishing expeditions"; and (3) provide notice of the claim. *Vicom, Inc. v. Harbridge Merchant Services, Inc.,* 20 F.3d 771, 777 (7th Cir.1994). However, although a plaintiff must plead the circumstances of the alleged fraud with particularity, "[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally."Fed.R.Civ.P. 9(b).

***13** Here, a careful review of the Complaint reveals that Extra has adequately pled facts setting forth "the identity of the person who made the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff."*General Elec. Capital,* 128 F.3d at 1078. For example, as set forth in detail above, Extra alleges that Mr. Cahill induced Extra to come to Illinois by leading Extra to believe that Mr. Sharman had authority to bind Case Brasil.

Based on this representation, on October 19, 1999, Mr. Briante flew to Waukegan, Illinois to meet with Sharman and Cahill. At this meeting, Sharman and Cahill: (1) "manipulated the corporate distinction between itself and Case Brasil" and (2) misrepresented that Mr. Sharman had authority to sign the agreement on behalf of Case Brasil, when he in fact did not. Likewise, the Agreement, drafted by Mr. Cahill, stated that Mr. Sharman had authority to bind Case Brasil.

Accordingly, this Court finds that Extra has pled sufficient facts to meet Rule 9(b)'s heighten pleading standard, and therefore, this Court DENIES the motion to dismiss on the grounds that the fraud claims do not comply with Rule 9(b).

IV. Motion to Strike

Case has also moved to strike paragraphs 33-36, 46-47, and 63-67 in the Complaint. Federal Rule of Civil Procedure 12(f) gives courts discretion to strike allegations in a complaint that are "immaterial, impertinent, or scandalous." Such motions, however, are "not favored" and will only be granted where the allegations have "no relation to the controversy and [are] unduly prejudicial."*Villalovos v. Sundance Assocs., Inc.,* 2003 WL 1152443, at *5 (N.D.Ill. Jan. 13, 2003). Allegations are "immaterial" for purpose of Rule 12(f) only if they have "no essential ... relationship to the claim[s]."*Chicago Printing Co. v. Heidelberg,* 2001 WL 1646567, at *1 (N.D.Ill.Dec.21, 2001). When determining whether an allegation is "immaterial" the court must consider whether the facts alleged "possib[ly] ... from the basis for admissible evidence."*Id.See also*Sutton Place Dev. Co. v. Green, 1987 WL 5951, at *1 (N.D.Ill. Jan.27, 1987) (allegations are only immaterial if they "have no possible bearing on the issues at trial"). Similarly, a matter is "impertinent if it is neither responsive nor relevant to the issues involved in the action."*Sutton Place Dev. Co.,* 1987 WL 5951, at *1. A "scandalous" allegation is one which "unnecessarily reflects upon the moral character" of the defendant. *Id.*

The burden to meet the above strong showing is on the movant, who must specifically explain why the paragraphs are repetitive, immaterial, or scandalous. *Id.* Even if such a showing is made, however, the motion should be denied if "the allegations might serve to achieve a better understanding of the claim ... or perform some other useful purpose in the just disposition of the litigation."*Woodson v. Cook Co. Sheriff*, 1996 WL 604051, at *5 (N.D.Ill. Oct.18, 1996).

***14** With the above standards in mind, the Court now turns to the specific paragraphs which Case seeks to strike. Paragraphs 33-36 and 46-47, detail the alleged improper conduct by Case Brasil officers (including the illegal charge backs to Extra) and Case's internal investigation into this conduct before signing the Agreement. Paragraphs 63-67 pertain to the information which Extra supplied to Case pursuant to the Waukegan Agreement and what Case did with this evidence, *e.g.,* it fired the corrupt Case Brasil employees. These allegations are relevant to Case's intent and motivation to defraud Extra and what benefits Case received under the Agreement. Accordingly, because these paragraphs supply relevant information and do not appear overtly prejudicial, this Court DENIES Case's motion to strike.

CONCLUSION

For the reasons discussed, this Court: (1) DENIES Defendant Case Corporation's Motion to Dismiss [28-1] with respect to the fraud claims (Counts I and III) but GRANTS it as to the negligent misrepresentation claim (Count II); and (2) DENIES Case's request to strike.

N.D.Ill.,2005.
Extra Equipamentos E Exportacao Ltda. v. Case Corp.
Not Reported in F.Supp.2d, 2005 WL 843297 (N.D.Ill.)

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APPENDIX 3

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Duramed Pharmaceuticals, Inc.,	)	
	)	Case No. C-1-00-735
Plaintiff,	)	
vs.	)	
Wyeth-Ayerst Laboratories, Inc.,	)	
Defendants.	)	

O R D E R

This matter is before the Court on Defendant Wyeth Ayerst-Laboratories, Inc.'s Motion to Dismiss and/or Strike (Doc. No. 11). For the reasons set forth below, Defendant's motion is **GRANTED IN PART AND DENIED IN PART.**

I. Background

The Plaintiff in this case is Duramed Pharmaceuticals, Inc. ("Duramed"). Duramed is a Cincinnati-based company which develops, manufactures, and markets prescription and over-the-counter drug products. Complaint ¶ 1. Defendant Wyeth-Ayerst Laboratories, Inc. ("Wyeth") is also a manufacturer and developer of pharmaceutical products. Id. ¶ 2. The parties are competitors in the business of selling conjugated estrogens for use in treatment of vasomotor symptoms (hot flashes and night sweats) in menopausal women.

Wyeth is the predominant manufacturer of conjugated estrogens in the United States. Wyeth has been manufacturing and marketing its conjugated estrogen, Premarin, since 1942. The name "Premarin" is derived from its primary ingredient - pregnant

mare's urine. See Complaint ¶ 13. Premarin is also indicated and FDA-approved for use in the treatment of osteoporosis. Id. According to the Complaint, Premarin is the most widely used prescription drug in America and enjoys a market share of 99% and annual sales of over $800 million. Id. ¶¶ 6, 16.

Duramed sought to develop its own conjugated estrogen product. Duramed's conjugated estrogen is a plant-based alternative, derived from soy and yam plants. Id. ¶ 17. Duramed first sought FDA approval of its product as an unbranded generic alternative to Premarin. Wyeth successfully petitioned the FDA against approval of Duramed's product as a generic. This forced Duramed to go through a more costly and time-consuming process to have its product approved as a brand name drug. Wyeth also petitioned the FDA to disapprove Duramed's application for a brand name conjugated estrogen. This time, however, Wyeth was unsuccessful and Duramed began marketing its conjugated estrogen, Cenestin, in March 1999. See id. ¶¶ 7-8. Although the Court will not go into the details here, Duramed claims that Wyeth engaged in a campaign of providing the FDA with false and misleading information in opposing Duramed's applications for approval of its conjugated estrogen as a generic, and later a brand name, prescription drug. See id. ¶¶ 7-8, 19-49.

Having failed to prevent the introduction of Duramed's conjugated estrogen through administrative channels, the Complaint alleges that Wyeth engaged in certain anti-competitive conduct in order to maintain a monopoly position in the market.

Specifically, the Complaint alleges that Wyeth has entered into contracts with managed care organizations, employers, and other entities offering health plans which prevent or limit these providers from making Cenestin available to their members. See Complaint ¶ 52. According to the Complaint, health plans control costs by implementing drug product formularies. A drug product formulary is a list of required, preferred, or recommended drugs for health plan members. Id. ¶ 53.

The Complaint states that over 70% of all Americans purchase their prescription drugs through formularies, and, because of that, successful marketing requires placement of the drug on as many formularies as possible. Id. ¶ 56. The Complaint further alleges that Wyeth holds contracts with most of the health plans and pharmacy benefits managers representing a majority of the covered lives in the country. These contracts, the Complaint says, provide that Premarin shall be the sole and exclusive conjugated estrogen on the formulary. The purpose and effect of these contracts, Duramed claims, is to prevent Cenestin from being dispensed to patients. Id. ¶ 58. The Complaint alleges that Wyeth has offered rebates, discounts, and other benefits to health plans and pharmacy benefits managers conditioned on Premarin being the sole and exclusive conjugated estrogen on the formulary. The rebates and discounts are based on the dollar or unit volume of sales of Premarin to plan members. Id. ¶ 59. The Complaint alleges that because of Premarin's huge market share, health plans would suffer enormous

financial losses if these incentives were denied. Therefore, health plans are faced with an imposing financial obstacle if they wish to offer Cenestin to their members. Id.

In addition to these overt exclusive contracts, the Complaint alleges that Wyeth has entered into "disguised" exclusive contracts which offer rebates or discounts if a health plan's use of Premarin is equal to or greater than Premarin's national market share. These same contracts also provide for financial penalties if Premarin sales drop below the national average. The Complaint also alleges that Wyeth advises health plans and pharmacy benefits managers that they will lose rebates and administrative fees if they add Cenestin to their formularies. Id. ¶¶ 60-61. Finally, the Complaint alleges that Wyeth has misrepresented the characteristics and therapeutic value of both Premarin and Cenestin in order to enhance the sales of Premarin and to maintain its monopoly power. Id. ¶ 62. In sum, the Complaint alleges that Wyeth's use of exclusive contracts prevents Duramed from competing effectively with Premarin in the market place and allows Wyeth to maintain a monopoly in the conjugated estrogens market. Id. ¶ 64.

On September 5, 2000, Duramed filed a four count antitrust Complaint (Doc. No. 1) against Wyeth under the Sherman Act, 15 U.S.C. § 1, et seq., and the Clayton Act, 15 U.S.C. § 12, et seq. Count I of the Complaint alleges that Wyeth has violated

Section 2 of the Sherman Act, 15 U.S.C. § 2,[1] by engaging in monopolization. Count I alleges that Wyeth is a monopolist because it has excluded competition in the relevant market through the behavior outlined above and has raised the price of Premarin above competitive levels. Count II of the Complaint also alleges that Wyeth has violated Section 2 of the Sherman Act by attempting to monopolize the relevant market. Count III of the Complaint alleges that Wyeth has violated Section 1 of the Sherman Act, 15 U.S.C. § 1,[2] because its exclusive contracts have resulted in unreasonable restraints on trade and competition.

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[1] Section 2 of the Sherman Act provides:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2.

[2] Section 1 of the Sherman Act provides:

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

Finally, Count IV of the Complaint alleges that Wyeth has violated Section 3 of the Clayton Act, 15 U.S.C. § 14,[3] because it conditions rebates, discounts and other incentives on the requirement that health care providers not use, deal in, or purchase Cenestin and the effect of such conduct substantially lessens competition and tends to create a monopoly in the relevant market.

Duramed seeks a declaration that Wyeth's conduct violates the antitrust laws cited, an award of actual and treble damages caused by Wyeth's alleged illegal conduct, an injunction prohibiting Wyeth from engaging in anti-competitive and exclusionary conduct, an award of attorney's fees, an award of the costs of the suit, and interest on damages.

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[3] Section 3 of the Clayton Act provides:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods, wares, merchandise, machinery, supplies, or other commodities, whether patented or unpatented, for use, consumption, or resale within the United States or any Territory thereof or the District of Columbia or any insular possession or other place under the jurisdiction of the United States, or fix a price charged therefor, or discount from, or rebate upon, such price, on the condition, agreement, or understanding that the lessee or purchaser thereof shall not use or deal in the goods, wares, merchandise, machinery, supplies, or other commodities of a competitor or competitors of the lessor or seller, where the effect of such lease, sale, or contract for sale or such condition, agreement, or understanding may be to substantially lessen competition or tend to create a monopoly in any line of commerce.

15 U.S.C. § 14.

On October 26, 2000, Wyeth filed a motion to strike and/or to dismiss the Complaint. See Doc. No. 11. In its motion, Wyeth moves the Court to strike those allegations in the Complaint relating to Wyeth's activities petitioning the FDA against Cenestin on the grounds that recovery on the basis of that conduct is barred by the Noerr-Pennington doctrine. In addition, Wyeth argues that Duramed has failed to state antitrust claims based on exclusive dealing because the contracts at issue are of short duration and are easily terminable, and, therefore, do not foreclose the market to competition.[4] Alternatively, Wyeth argues that because Duramed's claims are based on conduct that lowers the price of Premarin, Duramed must allege that Wyeth has engaged in predatory pricing. Duramed, however, has not alleged that Wyeth has engaged in predatory pricing. Therefore, Wyeth argues, Duramed has failed to state antitrust claims based on the exclusive contracts.

In response, Duramed seems to admit that recovery based on Wyeth's FDA petitioning activities is precluded, but argues that evidence of such activity would be admissible in order to show Wyeth's monopolistic intent. Therefore, Duramed argues, these allegations are properly included in the Complaint. With respect to Wyeth's other arguments, Duramed contends that whether

[4] The contracts themselves were not attached to the Complaint. Wyeth argues, however, that the Court may review the contracts on a Rule 12(b)(6) motion because the claims in the Complaint are based largely, if not exclusively, on those contracts. Nevertheless, Wyeth has not submitted any of these contracts with its moving papers.

an exclusive contract is of short duration and is easily terminable is but one factor, and not dispositive, on the issue of whether an exclusive contract violates the antitrust laws. In any event, Duramed argues that the Court may not review Wyeth's contracts without converting the present Rule 12(b)(6) motion into one for summary judgment. Finally, Duramed contends that it need not allege that Wyeth engaged in predatory pricing to prove a violation based on rebate and discount programs.

Wyeth's motion to strike and/or to dismiss has been fully briefed and is now ripe for disposition.

II. Rule 12(b)(6) Standard of Review

A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. In its consideration of a motion to dismiss under Rule 12(b)(6), the court is required to construe the complaint in the light most favorable to the Plaintiff and accept all well-pleaded factual allegations in the complaint as true. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) and Roth Steel Products v. Sharon Steel Corp., 705 F.2d 134, 155 (6th Cir. 1983). A court, however, will not accept conclusions of law or unwarranted inferences which are presented as factual allegations. Blackburn v. Fisk University, 443 F.2d 121, 124 (6th Cir. 1974). A court will, though, accept all reasonable inferences that might be drawn from the complaint. Fitzke v. Shappell, 468 F.2d 1072, 1076-77 n.6 (6th Cir. 1972).

When considering the sufficiency of a complaint pursuant to a Rule 12(b)(6) motion, this Court recognizes that "a

complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the Plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-6 (1957).

III. Analysis

The Court starts the analysis by addressing Wyeth's contention that certain allegations in the Complaint should be stricken under the Noerr-Pennington Doctrine before turning to the alleged insufficiency of Duramed's antitrust claims.

A. Noerr-Pennington Doctrine

As indicated, approximately thirty-three paragraphs of the Complaint deal with Wyeth's allegedly deceptive and misleading efforts before the FDA to prevent Duramed from introducing its own conjugated estrogen to the market. Wyeth contends that recovery based on these allegations is barred by the Noerr-Pennington doctrine while Duramed argues that the allegations are relevant in proving Wyeth's monopolistic intent.

The Noerr-Pennington Doctrine is derived from the Supreme Court cases Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961) and United Mine Workers v. Pennington, 381 U.S. 657 (1965). In Potter's Medical Center v. City Hospital Ass'n, 800 F.2d 568 (6th Cir. 1986), the Sixth Circuit explained the doctrine as follows:

> In Noerr and Pennington, the Supreme Court held that attempts to influence the legislative process, even if prompted by an anticompetitive intent, are immune from antitrust liability. This doctrine rests on two

> grounds: the First Amendment's protection of the right to petition the government, and the recognition that a representative democracy, such as ours, depends upon the ability of the people to make known their views and wishes to the government. Noerr, 365 U.S. at 137-38, 81 S.Ct. at 529-30. In California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 510, 92 S.Ct. 609, 611, 30 L.Ed.2d 642 (1972), the Supreme Court extended the protection of the Noerr-Pennington doctrine to efforts to influence administrative agencies and the courts. California Motor Transport also elaborated on the sham exception first alluded to in Noerr that some activity, ostensibly directed toward influencing governmental action, may be merely a "sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor," so as to justify application of the Sherman Act. Noerr, 365 U.S. at 144, 81 S.Ct. at 533. California Motor Transport recognized that "unethical conduct in the setting of the adjudicatory process" or the pursuit of "a pattern of baseless, repetitive claims" is unprotected by the Noerr-Pennington doctrine; such conduct "constitutes an abuse of [governmental] processes . . . effectively barring a competitor's meaningful access to the courts or agencies." 404 U.S. at 512-13, 92 S.Ct. at 612-13; accord Otter Tail Power Co. v. United States, 410 U.S. 366, 380, 93 S.Ct. 1022, 1030, 35 L.Ed.2d 359 (1973).

Id. at 578. The Court observes that Duramed does not claim that Wyeth's petitioning activities fall within the sham exception to the Noerr-Pennington Doctrine (even though Duramed characterizes Wyeth's conduct as deceptive and misleading). And, as the Court has noted, Duramed apparently concedes that it may not recover antitrust damages from Wyeth based on this conduct.

Nevertheless, Duramed argues that the challenged allegations are properly includable in the Complaint because they are relevant to showing Wyeth's alleged monopolistic intent. The Court disagrees. The Sixth Circuit addressed substantially the same argument in City of Cleveland v. Cleveland Elec. Illuminating Co., 734 F.2d 1157 (6th Cir. 1984). In that case,

the trial court, based on the Noerr-Pennington Doctrine, prohibited the plaintiff from admitting into evidence information about Cleveland Electric's secret sponsorship of a lawsuit challenging an order issued by the Federal Power Commission requiring Cleveland Electric to interconnect with a competitor, Muny Light. See id. at 1161. The Court of Appeals stated that:

> The City's effort to introduce the evidence was to show the anticompetitive character and nature of Cleveland Electric's conduct in this episode as a part of the alleged broader pattern of conduct condemned by the Sherman Act, and to cast appellee and its counsel in the role of deceivers. This is not an admissible basis for its introduction in our view.

Id. at 1163 (emphasis added). The Court further held that such evidence was also properly excludable under Federal Rule of Evidence 403. See id.; Fed. R. Evid. 403 ("Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."). Indeed, this holding makes eminent sense given that Noerr-Pennington provides immunity even where the defendant invokes the legislative process with monopolistic intent. Allowing an antitrust plaintiff to introduce evidence of the defendant's prior legislative petitioning as evidence of monopolistic intent is simply an end-around the doctrine.

In this case, Duramed asserts precisely the same grounds for the relevancy and admission of the challenged allegations as the Sixth Circuit rejected in Cleveland Electric.

See Doc. No. 14, at 19 ("Because of their relevance to Duramed's antitrust claims - to show Wyeth's intent to monopolize and the nature of its anticompetitive and exclusionary conduct - Wyeth's conduct alleged in paragraphs 7-8 and 19-49 of the Complaint cannot be stricken."). The Court finds that this case falls squarely within Cleveland Electric's proscription against admitting conduct protected by the Noerr-Pennington Doctrine as evidence of monopolistic intent. Accordingly, Wyeth's motion to strike is well-taken and is **GRANTED**. Paragraphs 7-8 and 19-49 are deemed **STRICKEN** from the Complaint.

B. Failure to State a Claim

As indicated, Wyeth argues that Duramed has failed to state antitrust claims because it has failed to allege that Wyeth has engaged in predatory pricing and because the exclusive contracts at issue are of short duration and easily terminable. Counsel for Wyeth states that most of its contracts are terminable at will in under 90 days. Duramed contends that the duration of the contract and its ease of termination are not dispositive of the issue and that it need not allege predatory pricing to state a claim based on exclusive dealing. The Court agrees with Duramed on both counts.

As an initial matter, the Court observes that even if it were to accept Wyeth's argument that exclusive contracts which are of short duration and easily are terminable are presumptively

legal,[5] the contracts have not been made a part of the record. Therefore, the Court has nothing but counsel's assurances that the contracts are what they are purported to be. Obviously, the Court cannot accept counsel's word on an issue potentially dispositive of the entire case. That alone would be enough to foreclose Wyeth's first argument.

Exclusive dealing contracts are not illegal per se. See Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 327 (1961). Rather, the question is whether performance of the contract will foreclose competition in a substantial share of the line of commerce affected. Id. In making this determination, the Court outlined several factors for consideration. First, the line of commerce, i.e., the goods, involved must be determined. Second, the area of effective competition must be ascertained by determining the seller's marketing area. And, third, the court must find that the competition foreclosed is a substantial share of the relevant market, i.e., that opportunities for other traders to enter into or remain in the market must be significantly limited. Id. at 628. To determine substantiality the court must weigh the probable effect of the contract on competition in the relevant market area, the relative strength of the parties, the proportion of commerce involved compared to the total volume of commerce in the relevant market area, and the probable effects which preemption of that share of the market

[5] This, of course, also assumes that the Court could properly review the contracts on a Rule 12(b)(6) motion.

might have on competition within the market. Id. at 329. In that particular case, the Court found that the exclusive contract was legal, even though it had a duration of 20 years, because the contract involved an insignificant proportion of the total volume of coal in the relevant market. See id. at 330-34.

The only case the Court has found that has explicitly adopted Wyeth's position is Roland Machinery Co. v. Dresser Ind., Inc., 749 F.2d 380 (7th Cir. 1984), in which Judge Posner held that "[e]xclusive dealing contracts terminable in less than one year are presumptively lawful[.]" See id. at 395. Other than Roland Machinery, the Court's review of the cases tends to indicate that the duration of the contract is but one factor for consideration. See, e.g., Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1058-1060 (8th Cir. 2000); Omega Environmental, Inc. v. Gilbarco, Inc., 127 F.3d 1157, 1162-65 (9th Cir. 1997); Balaklaw v. Lovell, 14 F.3d 793, 798-800 (2nd Cir. 1994); U.S. Healthcare, Inc. v. Healthsource, Inc., 986 F.2d 589, 595-97 (1st Cir. 1993). Therefore, the Court holds that the duration of the contract and whether it is easily terminable are merely factors for considering whether competition is substantially foreclosed.

Wyeth's next contention is that Duramed has failed to allege that its discount and rebate programs have resulted in predatory pricing. Therefore, Wyeth contends, Duramed has failed to allege any antitrust injury. Predatory pricing occurs when a single firm, having a dominant share in the relevant market, cuts prices in order to force competitors out of the market or to

perhaps deter future competitors from coming in. See Matsushita Elec. Ind. Co. v. Zenith Radio Corp., 475 U.S. 574, 584 n.8 (1986). The Supreme Court has cautioned that predatory pricing claims are rarely successful because lowering prices usually stimulates, and not inhibits, competition. Brooke Group, Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 226 (1993). The Court agrees with Wyeth that Duramed has not alleged that Wyeth's discounts and rebates resulted in predatory pricing. The Court, however, does not view Duramed's Complaint as asserting pure predatory pricing schemes. Rather, it appears that Duramed alleges that Wyeth has offered discounts and rebates in order to entice health plans into entering into overt exclusive dealing contracts or that the discount programs themselves are de facto, or "disguised" exclusive dealing contracts because the incentives are too attractive, or in the alternative, too punitive, financially to pass up. See Complaint ¶¶ 59-60. The alleged result of the discounts is not predatory pricing but rather foreclosure of the market. Therefore, although Duramed's theory of the case may require further explication, the Court believes that Duramed has sufficiently stated a claim for relief without alleging that Wyeth has practiced predatory pricing.

Furthermore, the Court agrees with Duramed that it has sufficiently pled foreclosure of the market. The Court observes that Duramed alleges that Wyeth possesses 99% of the relevant market share, that most if not all of the outlets for Duramed's product are tied up by Wyeth's exclusive contracts, and that

there are significant barriers to entry in the relevant market, such as obtaining FDA approval, outstanding patents on other branded drugs and accessing formularies. See Complaint ¶ 71. The Court also assumes that research and development costs present a significant barrier to entry. Concord Boat, 207 F.3d at 1059 (considering barriers to entry in market foreclosure analysis). Therefore, the Court finds that Duramed has sufficiently stated claims for antitrust violations.

Accordingly, Wyeth's motion to dismiss Duramed's claims is not well-taken and is **DENIED.**

IT IS SO ORDERED

Date 8-1-01

Sandra S. Beckwith
United States District Judge

APPENDIX 4

Westlaw.
Not Reported in F.Supp.
Not Reported in F.Supp., 1992 WL 220638 (N.D.Ill.)
(Cite as: Not Reported in F.Supp.)

Genderm Corp. v. Biozone Laboratories
N.D.Ill.,1992.
Only the Westlaw citation is currently available.
United States District Court, N.D. Illinois, Eastern Division.
GENDERM CORPORATION, Plaintiff,
v.
BIOZONE LABORATORIES, a California corporation, Defendant.
No. 92 C 2533.

Sept. 3, 1992.

MEMORANDUM OPINION AND PRELIMINARY INJUNCTION ORDER

I. INTRODUCTION

HART, District Judge.
***1** This matter is before the court on the motion of plaintiff GenDerm Corporation ("GenDerm") for a preliminary injunction to restrain defendant BioZone Laboratories ("BioZone") from engaging in alleged false advertising and trademark infringement. After denying a temporary restraining order, the motion for a preliminary injunction was referred to Magistrate Judge Pallmeyer for an evidentiary hearing, a report and a recommendation. Hearings were held, and on June 12, 1992 the magistrate judge filed a report and recommended preliminary relief. On July 7, 1992, BioZone filed objections. On July 15, 1992, GenDerm filed a response to those objections.

The report of the magistrate judge is comprehensive and carefully considers the positions of the parties. The report is adopted and attached hereto as an appendix.

II. OBJECTIONS TO THE REPORT

Capsaicin is a chemical compound that occurs within the capsicum family of hot red peppers. For a number of years, GenDerm has used an extract called capsaicin in a 0.025% concentration in its over-the-counter topical analgesic product, ZOSTRIX.® In March 1992, BioZone began marketing a competing topical analgesic under the name CAPTRIX. BioZone labeled and promoted CAPTRIX as also containing 0.025% capsaicin as its active ingredient. GenDerm's initial complaint alleged patent infringement, trademark infringement, unfair competition under the Lanham Act and the common law and violations of Illinois and California state law.

After the filing of this action, GenDerm discovered, by tests of CAPTRIX, that the active ingredient is not capsaicin but a compound with a different composition, formula and chemical weight. On May 13, GenDerm withdrew its patent infringement claim but added further claims of false labeling and false advertising. These matters were the subject of a hearing.

The magistrate judge has found that CAPTRIX is falsely labeled; falsely advertised; bears an infringing trademark; and contains an active ingredient that has not been tested on humans or approved for use in the United States.

A. Request for an Additional Hearing

Initially, BioZone argues that it is entitled to a *de novo* evidentiary hearing before the court at which it desires to offer additional proofs. Federal Rule of Civil Procedure 72(b) requires that the court make a *de novo* determination upon the record and that it consider objections to a report. However, the court is not required to conduct a *de novo* hearing of evidence. *United States v. Raddatz,* 447 U.S. 667, 678-80 (1980); *Advance Coating Technology, Inc. v. LEP Chemical Ltd.,* 142 F.R.D. 91, 93-94 (S.D.N.Y.1992). Moreover, there is nothing asserted in the requests for additional hearing that could not have been submitted during the hearing before the magistrate judge. The court declines, therefore, to conduct an additional evidentiary hearing.[FN1]

B. BioZone's False Label and Package Insert

ZOSTRIX contains capsaicin (C18) as its active ingredient. CAPTRIX contains a product described by the experts as nonivamide (C17) or pelargonic acid vanillylamide. Although, in its supplemental filings, BioZone seeks to question the use of the

name nonivamide, its position does not affect the accuracy of the findings.

***2** BioZone has stated that the active ingredient in CAPTRIX has the molecular weight 305.4 and the formula C18H27NO3 and the structure of capsaicin. In fact, the nonivamide in CAPTRIX has the molecular weight 293.4 and the formula C17H27NO3. The product is synthetically derived and not an extract of capsicum hot pepper plants. Also, contrary to the product claim, there is no USP standard for C17.

It has been stated by BioZone that CAPTRIX is the pharmacological equivalent of GenDerm's product ZOSTRIX. However, there is no support for this claim. No testing has been conducted.

BioZone concedes that it has made false representations but contends that they were not material or injurious. However, as the magistrate judge correctly held, false statements are presumed to be material. Section 43(a)(2) of the Lanham Act prohibits the use of false or misleading representations, and there is a well established presumption that injuries arising from Lanham Act violations are irreparable. *Abbott Laboratories v. Mead Johnson & Co.,*--- F.2d ---- (7th Cir. July 23, 1992).

C. A Change in the CAPTRIX Label and Package Insert

BioZone's offer to change its promotional statements and label as a part of its objections, and in order to avoid an injunction, comes too late. *United States v. W.T. Grant Co.,* 345 U.S. 629, 632-33 (1953); *Hard Rock Cafe Licensing Corp. v. Concession Services, Inc.,* 955 F.2d 1143, 1151 (7th Cir.1992); *Scotch Whiskey Association v. Barton Distilling Co.,* 489 F.2d 809, 813 (7th Cir.1973). However, its offer will be considered in connection with any relief granted.

D. The CAPTRIX Mark Infringes GenDerm's ZOSTRIX Mark

The magistrate judge correctly found and concluded that the competing marks share a common suffix and pronunciation; are similar in appearance as presented on the parties' products; compete with each other in identical channels of commerce; and are recommended to patients by physicians or pharmacists based upon package data. GenDerm has shown a likelihood of success on its trademark infringement claim.

On August 26, 1992, BioZone informed the court that it has changed the name of its product to "BioZone Topical Analgesic Cream."

E. Jurisdiction of the FDA

BioZone argues that the approval of its product and the interpretation of the FDA publication on external analgesics are matters within the exclusive jurisdiction of the Food and Drug Administration pursuant to the Food, Drug and Cosmetic Act. Here the magistrate judge has not, and this court does not, make a novel interpretation or any interpretation of the FDA's monograph on external analgesics as it may apply to nonivamide or "pelorganic acid vanillylamide." It is merely concluded that C17 has never been used in a drug in the United States previously, has never been tested on humans and is not listed in the FDA monograph. Accordingly, what is here involved is the propriety of a Lanham Act preliminary injunction based on false statements. *See Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.,* 720 F.Supp. 714, 716 (N.D.Ill.1989) (orange juice); *McNeill-P.C.C., Inc. v. Bristol-Myers Squibb Co.,* 938 F.2d 1544, 1549 (2d Cir.1991) (over-the-counter analgesics); *Upjohn Co. v. Riahom Corp.,* 641 F.Supp. 1209, 1222-23 (D.Del.1986) (untested hair growth product claimed to be a cosmetic not a drug).

III. BALANCE OF EQUITIES

***3** The court agrees with the analysis of the magistrate judge which indicates that preliminary relief is appropriate.

The magistrate judge found that GenDerm has spent substantial sums in testing and promotional costs. Defendants have invested nothing in testing and have attempted to take a market share by false statements. BioZone has an investment of $10,000 in a product which could produce $55,000 in gross sales. Between ten and fifteen thousand units have been sold.

As indicated by the Court of Appeals in *Abbott Laboratories v. Mead Johnson & Co.,*--- F.2d ---- (7th Cir. July 23, 1992), this court should and will consider preliminary injunctive relief tailored to prevent harm to the plaintiff with the least structures appropriate, taking into account BioZone's offer to alter its promotional material.

For the reasons stated in the report, the magistrate judge correctly rejected BioZone's "unclean hands" defense to injunctive relief.

IV. Requirement for a Bond

Neither party addresses the appropriate amount of a bond required by Fed.R.Civ.P. 65(b) upon the issuance of a preliminary injunction. Considering the small investment and recent entry into the market by BioZone, a bond in the amount of $75,000 is judged to be adequate to protect the interests of BioZone.

IT IS THEREFORE ORDERED as follows:

1. Defendant BioZone's objections to the magistrate judge's report are overruled and its request for additional evidentiary hearing on plaintiff's motion for a preliminary injunction is denied. Defendant's motion for leave to file clarification by declarant is denied.

2. Pending further order of this court, defendant BioZone Laboratories is preliminarily enjoined as follows:
A. From selling the product that had been marketed as CAPTRIX without stating on the label and any package insert that the active ingredient is pelargonic acid vanillylamide and, to the extent the chemical formula structure or molecular weight is included, such formula or weight shall not be stated to be capsaicin, C18H27NO3, or as having a molecular weight of 305.4.
B. From using the word "capsaicin" alone or with any other term including "synthetic" on its product, and from stating that its active ingredient is purified under U.S.P. standards.
C. From making any advertisements or oral representations comparing its product with ZOSTRIX including statements that they are equivalent or that its product may be substituted for ZOSTRIX.
D. BioZone is ordered to recall all falsely labeled product and inserts for the correction of inaccurate statements as found in this proceeding.
E. BioZone is ordered to submit to this court, on notice and motion, for prior approval, any BioZone promotional advertising material that mentions ZOSTRIX.

3. Within 48 hours of the date of this order, GenDerm Corporation shall file with the Clerk of the Court a surety bond in the amount of $75,000.

4. This case is set for a hearing on status on September 14, 1992 at 9:30 a.m.

APPENDIX

REPORT AND RECOMMENDATION

***4** Capsaicin is a chemical compound that occurs naturally within capsicum, the dried ripe fruit of certain red peppers. For several years, Plaintiff GenDerm Corporation has used capsaicin in a 0.025% concentration in its over-the-counter topical analgesic product, ZOSTRIX®. Beginning in March 1992, Defendant BioZone Laboratories marketed its own topical analgesic, CAPTRIX™, as a direct competitor of ZOSTRIX. BioZone labeled and promoted CAPTRIX as also containing 0.025% capsaicin as its active ingredient.

Plaintiff GenDerm filed its original complaint in this action on April 14, 1992 and a first amended complaint on April 22, 1992. GenDerm's first two complaints charged Defendant BioZone with patent infringement, trademark infringement, unfair competition under the Lanham Act and common law, and violations of Illinois and California state law. Soon after the filing of GenDerm's first amended complaint, tests of the CAPTRIX product performed at GenDerm's direction revealed that the active ingredient in CAPTRIX is not capsaicin but a closely related compound, nonivamide. Nonivamide is synthetically produced and has a chemical formula, composition, and chemical weight different from capsaicin's. On May 13, 1992, GenDerm filed a second amended complaint in which it withdrew the patent infringement claims but added further claims that BioZone was guilty of false labeling and false advertising.

GenDerm's motion for preliminary injunction was

referred by District Judge William T. Hart on April 28, 1992. Following a four-day hearing completed on June 1, 1992, the parties submitted proposed findings of fact and conclusions of law.[FN1] For the following reasons, it is recommended that GenDerm's motion for preliminary injunctive relief be granted.

FINDINGS OF FACT

1. Plaintiff GenDerm was founded in 1983 by Joel Bernstein, M.D. GenDerm develops and markets pharmaceutical products for the treatment of pain and certain skin diseases. One of its most successful products is a topical analgesic cream, ZOSTRIX, which is the subject of this litigation. GenDerm employs a twenty-five person research and development staff and has participated in more than ten clinical studies for approval of its products by the Food and Drug Administration ("FDA"). ZOSTRIX and a related product known as ZOSTRIX HP account for approximately 70% of the company's current world-wide sales, which for the year 1991 totalled slightly less than $20 million.

2. Defendant BioZone Laboratories is a California partnership founded in 1989 by Brian Keller, a doctor of pharmacy, and Daniel Fisher, a computer software sales representative who had no previous experience in the pharmaceutical industry. Other than Dr. Keller and Mr. Fisher, BioZone has only a single part-time employee. Since March 1992, BioZone had distributed a topical analgesic cream called CAPTRIX, which BioZone states contains "capsaicin 0.025% weight-by-weight." As of September 1990 (the date of its last financial statement), BioZone had earned less than $30,000 in sales. BioZone conducts no laboratory or clinical testing and has never even tested its CAPTRIX product, except that each of the partners applied the cream to his own skin for a few days.

***5** 3. Dr. Bernstein has been involved in research involving capsaicin since his days as a graduate fellow in the late 1970's at the University of Chicago and later as a faculty member there and at Northwestern University. Dr. Bernstein developed the commercial ZOSTRIX product prior to 1987. It contains 0.025% of the active ingredient capsaicin by weight. ZOSTRIX HP contains 0.075% capsaicin by weight. Capsaicin is derived from the capsicum family of plants, commonly known as hot pepper plants. The natural substance extracted from the plant, called capsicum oleoresin, has been used by humans for hundreds of years. Capsaicin, which is extracted from capsicum, began to be used alone as an external analgesic in about 1981. Capsaicin is the common name of a single, specific compound. It has the unique Chemical Abstract Service ("CAS") No. 404-86-4 and is defined in the *Merck Index,* an authoritative text on the identity and definition of chemical compounds, as C18H27NO3. The *Merck Index* lists capsaicin's molecular weight as 305.4 and includes a drawing of capsaicin's specific chemical structure. The powder containing capsaicin that GenDerm uses in ZOSTRIX is purified from capsicum and contains approximately 65% capsaicin and 35% dihydrocapsaicin, another naturally-occurring compound.

4. ZOSTRIX is sold in a tube and packaged in a box containing an informational package insert. The box, tube, and package insert all indicate that the analgesic contains a single active ingredient, capsaicin 0.025%. According to its labeling, ZOSTRIX is intended "for the temporary relief of peripheral neuralgias such as the pain following shingles (herpes zoster)" and "for the temporary relief of the pain asociated with rheumatoid arthritis and osteoarthritis." Prior to its introduction on the market, ZOSTRIX was the subject of $1 million worth of testing and development by GenDerm. Since ZOSTRIX was introduced in 1987, GenDerm has spent $3 million to $4 million in continuing technical studies and more than $9 million in promoting the product through the publication of journal advertisements, the distribution of samples, and the sponsoring of continuing education programs for physicians. GenDerm has sought, in part through these efforts, to overcome the initial skepticism of physicians about the effectiveness of a topical pain relief product.

5. GenDerm maintains a sales staff at a cost of $3.4 million annually. GenDerm's sales staff devotes approximately one-third of its time to sales of ZOSTRIX and ZOSTRIX HP. ZOSTRIX directs its promotional efforts at physicians and pharmacists. Although ZOSTRIX is an over-the-counter product, it is known as an "ethical drug," that is, a product targeted primarily at physicians and pharmacists rather than users. Physicians ordinarily recommend the use of ZOSTRIX to a patient either verbally or by a written note or prescription. Of the 70 to 75

thousand tubes of ZOSTRIX sold each month, GenDerm's president, Frank Pollard, estimates that at least 75% are sold as a result of physicians' or pharmacists' prescriptions or recommendations. GenDerm holds federal and Illinois state trademark registrations for the mark ZOSTRIX.

***6** 6. BioZone Laboratories introduced its CAPTRIX product to the market in March 1992. Like ZOSTRIX, CAPTRIX is also sold in Illinois. BioZone asserts that CAPTRIX contains "capsaicin 0.025% weight-by-weight." In fact, however, CAPTRIX's active ingredient is not identical chemically to ZOSTRIX's. The active ingredient in CAPTRIX instead has the molecular formula C17H27NO3, a molecular weight of 293.41, a chemical structure different from capsaicin's, and a different CAS number, 2444-46-4. Although some chemical suppliers refer to this compound as "synthetic capsaicin," the proper chemical name for the compound is perlargonic acid vanillylamide. The accepted United States Adopted Names ("USAN") common name for pelargonic acid vanillylamide is nonivamide. Nonivamide is a synthetic product and is less expensive than capsaicin. (Dr. Keller testified that nonivamide occurs naturally in capsicum; but according to the more credible testimony of Dr. Dennis West, if nonivamide is present in capsicum at all, it is present only in trace amounts.) The term "synthetic capsaicin" does not appear in recognized pharmaceutical references, nor in two monographs published by the FDA in 1979 and 1983 relating to topical analgesics. Dr. Keller himself testified that the term "synthetic capsaicin" does not appear in pharmaceutical texts and that pharmacists are not familiar with the term. Expert testimony demonstrated that pharmacists are likely to believe that the C18H27NO3 compound is the active ingredient in CAPTRIX.

7. CAPTRIX, like ZOSTRIX, is sold in a tube and packaged in a box which contains a package insert. The box, tube, and package insert all identify the single active ingredient in CAPTRIX as capsaicin 0.025%. Like ZOSTRIX, CAPTRIX is sold "for the temporary relief of minor aches and pains of muscles and joints associated with arthritis and for pain associated with peripheral neuralgias." The labeling on the box also identifies CAPTRIX's active ingredient as "purified, USP"-an accepted reference to the United States Pharmacopeia, a private institution that establishes standards of drug purity. There is in fact no USP purity standard for either nonivamide or capsaicin.

8. The package insert for CAPTRIX states that its active ingredient, capsaicin, "is the pungent principle in fruit of various species of Capsicum, Solanaceae," is defined by the chemical formula C18H27NO3 (hereinafter, "C18"), has a molecular weight of 305.4, and is described by the chemical structure reproduced in the *Merck Index.* These statements do not accurately describe the actual active ingredient in CAPTRIX, nonivamide (hereinafter sometimes "C17"). Nonivamide, a synthetic product, has a different empirical formula, a different molecular weight, and a different chemical structure than capsaicin. Brian Keller, the doctor of pharmacy who is one of BioZone's two partners, knew before the marketing of the CAPTRIX product that CAPTRIX's active ingredient was not identical to the C18 compound. He acknowledged at the hearing that the package insert for BioZone's CAPTRIX product is erroneous. Although Dr. Keller testified that the package insert would be revised, he indicated that BioZone had not made a decision about the wording of the new package insert and what claims would or would not be made.

***7** 9. The CAPTRIX package insert specifically states that the product provides relief by blocking the release of substance P and neuropeptides in nerve receptors. The evidence BioZone relied on in support of this claim, however, was a study performed on ZOSTRIX, not CAPTRIX. At the time CAPTRIX was marketed, no product marketed in the United States had ever contained nonivamide as its active ingredient. Before CAPTRIX was marketed, Dr. Keller was not aware of any studies or tests suggesting that nonivamide is similar to capsaicin in terms of its safety or efficacy. Thus BioZone prepared the package insert for CAPTRIX without any knowledge of the chemical structure of CAPTRIX's actual active ingredient. BioZone began selling CAPTRIX without any testing and without knowing the characteristics of the vehicle (the non-active ingredients in which the active ingredient is suspended) in CAPTRIX. In fact, at the time that BioZone began selling CAPTRIX, Keller knew that the listing of the empirical formula for the active ingredient in the CAPTRIX package insert was wrong and that the labeling of CAPTRIX's active

ingredient as "purified, USP" was inaccurate. Only after the filing of this litigation did Dr. Keller read the article upon which BioZone now relies to predict that CAPTRIX's efficacy and safety is similar to that of ZOSTRIX.

10. Existing published reports of research on laboratory animals suggest that there are pharmacological differences between nonivamide and capsaicin. No scientific evidence supports the claims that the efficacy of the analgesic properties of CAPTRIX and ZOSTRIX are identical or that CAPTRIX is safe and efficacious.

11. Neither BioZone's chief distributor of CAPTRIX, McKesson Telemarketing Service, nor its FDA compliance counsel, Jay Geller, knew until after the filing of this litigation that CAPTRIX contains nonivamide and not capsaicin.

12. In contending that ZOSTRIX and CAPTRIX are equivalent, BioZone chiefly relies on an article about capsaicin that appeared in a recent issue of the journal Critical Reviews in Food Science and Nutrition.[FN2] According to this article, the C17 compound and the C18 compound are structurally very similar and have similar, although not identical, characteristics of "pungency, pain, and desensitization." CAPTRIX had never been tested, however, either in comparison with ZOSTRIX or with the performance of a placebo.

13. Approximately 10,000 of the 15,000 units of CAPTRIX produced have already been sold. The cost to BioZone of the remaining 5,000 units of CAPTRIX in its inventory is approximately $5,000.00. The total revenue BioZone would expect to receive from the sale of this inventory is $55,000.00. BioZone can ascertain the identity of the wholesalers and retailers that have received the CAPTRIX product. In addition to its inventory of packaged CAPTRIX tubes, BioZone also has in its possession approximately $5,000.00 worth of unfilled CAPTRIX boxes and tubes, identical in appearance to those in evidence. Their labels contain the same statements and claims as those on the packaged tubes. BioZone has no other inventory relating to the CAPTRIX product.

***8** 14. BioZone distributed approximately 100 of 500 promotional flyers it had printed. These flyers were sent to Long Drug Stores, McKesson Telemarketing Service, and possibly some members of the media. The flyer pitches CAPTRIX as an alternative to ZOSTRIX and states that "9 out of 10 physicians who currently prescribe capsaicin based products would prescribe CAPTRIX to their patients." The survey upon which this claim is based in fact consisted of an interview with ten physicians who were asked not to choose an independent preference based on their own comparison but rather to assume that CAPTRIX and ZOSTRIX were equally efficacious and that CAPTRIX was cheaper. The CAPTRIX flyer states, further, that "no other OTC [over-the-counter] topical pain reliever is more effective." No clinical study or other data supports this claim. The CAPTRIX flyer states, further, that "CAPTRIX has achieved significantly better results, when compared to counterirritants, in reducing the pain of arthritis." This claim is literally false because no test comparing CAPTRIX to counterirritants in reducing the pain of arthritis, or for any other purpose, was ever conducted. Finally, the CAPTRIX flyer states that "CAPTRIX provides immediate pain relief and unsurpassed long term pain relief by reducing the transmission of pain." This claim is not supported by any evidence, including the purported "testing" performed by Dr. Keller and Mr. Fisher-neither of whom suffers from arthritis or shingles-on their own bodies that lasted no more than a few days.

15. BioZone also distributed to the CAPTRIX sales force a document entitled "Selling Tips" in which BioZone states, "CAPTRIX cream is a nationally branded substitution for ZOSTRIX cream." At the time the document was drafted, however, BioZone's partners knew of no studies comparing capsaicin to nonivamide. No studies to date have compared CAPTRIX to ZOSTRIX. The "Selling Tips" document further stated:
CAPTRIX has achieved significantly better results, when compared to counterirritants and placebo in reducing pain of arthritis. Compared to placebo capsaicin showed a 33% reduction in pain from osteoarthritis and a 57% reduction in pain from rheumatoid arthritis.

In fact, CAPTRIX has never been tested against a counterirritant or placebo. The percentage figures quoted above actually appear in a report of a study conducted on ZOSTRIX.

16. Finally, BioZone published a "CAPTRIX Fact Sheet" for its distributors, including McKesson. The fact sheet represents that the active ingredient of CAPTRIX is capsaicin 0.025% and identifies the active ingredient as being "a naturally occurring substance derived from plants." The fact sheet states, further, that "ZOSTRIX offers no advantage to CAPTRIX." This claim suggests that ZOSTRIX and CAPTRIX have been clinically compared, when in fact no such study has been conducted.

17. In December 1979, the FDA proposed a monograph on external analgesic drug products. The FDA sought to establish conditions under which such products would be recognized as safe and effective for certain indicated uses and could be sold without prescription. In February 1983, the FDA issued a notice of proposed ruling in the form of a tentative final monograph. Under the 1983 monograph, the FDA would recognize certain external analgesic drug products as safe and effective for sale without a prescription, for the uses indicated. According to the 1983 monograph, subsequently codified at 21 C.F.R. § 348.12, drug products containing "capsaicin" or other "capsicum preparations" are recognized as safe and effective for over-the-counter sale as external analgesics, so long as those products are labeled for "the temporary relief of minor aches and pains of muscles and joints" associated with simple backache, arthritis, strains, bruises or sprains (*see*21 C.F.R. § 348.50(b)(1)). Although neither the 1979 proposed monograph nor the 1983 tentative final monograph defined the chemical structure of capsaicin, the *Merck Index* did include a drawing of capsaicin's specific chemical structure.

***9** 18. A number of over-the-counter topical analgesic products contain capsicum as their active ingredient. Only ZOSTRIX and CAPTRIX compete in the ethical topical analgesic market, however. Although both ZOSTRIX and CAPTRIX are sold over-the-counter and without a prescription, the products are usually recommended by a physician or pharmacist because arthritis and shingles normally are diagnosed by a physician. When a pharmacist recommends an over-the-counter drug to a patient, or attempts to provide a patient with an over-the-counter drug recommended by the patient's physician, the pharmacist relies on his or her identification of specific active ingredients that are listed on the labels of commercial products. The labeling of CAPTRIX would lead pharmacists to conclude that its active ingredient is identical to that of ZOSTRIX. A pharmacist is likely to substitute a less expensive product for a more expensive one if he or she believes that the cheaper product contains the same active ingredient. A pharmacist might conclude from CAPTRIX's labeling that CAPTRIX is equivalent to ZOSTRIX and, consequently, recommend the lower-priced CAPTRIX to patients whose physicians have directed them to obtain a topical analgesic containing 0.025% capsaicin. The fact that BioZone refused to disclose the true active ingredient to its distributors supports a conclusion that BioZone recognized the value of this potential confusion and hoped to benefit from it.

19. Similarly, as suggested by the ten-physician interview conducted on behalf of BioZone, a physician who would mistakenly believe that CAPTRIX contains the same amount of the same active ingredient as ZOSTRIX is likely to recommend the less expensive CAPTRIX product to a patient. It is reasonable to conclude, therefore, that every purchase of CAPTRIX would result in one fewer purchase of ZOSTRIX.

20. If the untested active ingredient in CAPTRIX proves ineffective or even harmful, GenDerm is likely to suffer damage to its reputation. For example, a dissatisfied customer of CAPTRIX-who would have no reason to believe that CAPTRIX contains anything other than the active ingredient capsaicin 0.025%- would be most unlikely to try ZOSTRIX or to recommend it to others. Moreover, a pharmacist or physician who learns of dissatisfaction on the part of any customer or patient resulting from the product's ineffectiveness or unintended side effects would be most unlikely to recommend ZOSTRIX to other customers or patients out of concern that ZOSTRIX contains the same amount of the same active ingredient as CAPTRIX.

21. The public may also be harmed if patients mistakenly purchase CAPTRIX out of a belief that it is identical to ZOSTRIX. The active ingredient in CAPTRIX has never been tested or approved. Users of CAPTRIX may possibly experience side-effects or harmful reactions from the interaction of CAPTRIX ingredients with other drugs in their body systems. If the active ingredient in CAPTRIX is safe but less effective than the C18 compound, the physician,

pharmacist, or patient (or all three) may conclude that a topical pain reliever does not effectively treat the pain. They may then turn to pain relievers having a higher degree of risk or side effects than GenDerm's product (or any other topical analgesic which may contain capsaicin 0.025%). Because CAPTRIX has only been on the market since March 1992, several months may pass before any of these potential harms manifest itself.

***10** 22. A pharmaceutical manufacturer must ordinarily seek FDA approval before introducing a new drug into the market. The FDA's master list shows that the ingredient nonivamide (or pelargonic acid vanillylamide) has never been the subject of a new drug application. Even without a new drug application, a drug may be placed on the market if it is generally recognized as safe and effective. In order to fall within this exception, however, a body of independent experts must determine on the basis of published reports that the drug is generally recognized as safe and effective. This published scientific data must be of substantial quantity and reflect the same quality as that required for approval of a new drug application itself, including the results of tests on humans. No data exists which would satisfy this standard for nonivamide. A second exception to the requirement for a new drug application is available for those over-the-counter drugs identified by the FDA's monographs. While the FDA's December 4, 1979 monograph for external analgesics does list capsaicin and capsicum, it does not list nonivamide, pelargonic acid vanillylamide, nor "synthetic capsaicin."

23. As more fully discussed in the Conclusions below, GenDerm has demonstrated that the Defendant's mark CAPTRIX is likely to be confused with the ZOSTRIX mark. The marks share a common suffix and are pronounced similarly, with emphasis on the first syllable. The products themselves contain an identical cream substance, are designed for identical use, and are marketed in identical channels of commerce. Further, Brian Keller knew of the ZOSTRIX mark at the time he selected the similar CAPTRIX mark. Although Defendant argues that the "-TRIX" suffix has been used in numerous prior registrations and other references, there is no evidence of such prior use in the over-the-counter topical analgesic market.

24. Before marketing its ZOSTRIX product, GenDerm consulted with its FDA counsel and former Chief Counsel for the FDA, Peter Hutt, to review the proposed labeling for ZOSTRIX against the 1979 and 1983 monographs for external analgesic over-the-counter drugs. Mr. Hutt believed that the labeling for ZOSTRIX complied with existing FDA law and regulations. Nevertheless, in January 1988 the FDA wrote to GenDerm objecting to the claim on the ZOSTRIX label that the analgesic provides "temporary relief of pain (neuralgia) associated with and following episodes of shingles (herpes zoster)." After receiving this letter, Mr. Hutt and Dr. Bernstein met with four FDA employees, including Ray Apodaca, chief of the FDA's Compliance Division, in the FDA's Washington office. At this meeting, Mr. Hutt and Dr. Bernstein explained GenDerm's position that its labeling of ZOSTRIX for a "targeted use" was authorized by the 1979 and 1983 monographs. The FDA took no further regulatory action until June 1991, at which time the FDA's Chicago district office sent GenDerm a warning letter concerning the claim on ZOSTRIX label assuring pain relief from herpes zoster. Mr. Hutt responded to the warning letter, this time drafting for GenDerm's president's signature a letter reiterating GenDerm's position and describing the 1988 meeting with Mr. Apodaca. GenDerm has heard nothing further from the FDA since June 1991.

***11** 25. The July-August 1991 edition of the official FDA magazine, FDA Consumer, contains an article written by a former FDA employee, Ken Flieger, who states:

Capsaicin cream (ZOSTRIX) has been reported by investigators at the pain clinic of Toronto Hospital to reduce pain in a significant percentage of PHN [Post-Herpetic Neuralgias] victims. The researchers say that more than half (56 percent) of PHN patients who received capsaicin cream for four weeks had good or excellent pain relief, and that 78 percent noted at least some improvement in pain.

Although capsaicin is an over-the-counter drug sold for muscular aches and pains, patients should consult a physician before using it to treat PHN. [FN3]

Although FDA consumer articles do not reflect official agency policy, FDA staff members do review articles before publication to insure consistency with agency policy. Mr. Hutt staff concluded that the publication of the statements quoted above suggests that the FDA no longer condemns the claims asserted

by ZOSTRIX to treat patients suffering from herpes zoster.

26. All of GenDerm's promotional materials and product efficacy claims are reviewed prior to their release by GenDerm's president, its vice-president of sales, its director of regulatory affairs, and its medical department. All claims appearing on ZOSTRIX's labeling and packaging are similarly reviewed. GenDerm adopted the ZOSTRIX labeling in good faith and in reliance on the advice of competent counsel.

CONCLUSIONS OF LAW

Jurisdiction and Venue

1. This court has jurisdiction over the federal trademark claims pursuant to 28 U.S.C. § 1338(a)(b) (1988). The court has jurisdiction over the unfair competition claims pursuant to 15 U.S.C. § 1114. Because these claims involve federal questions, the court also has jurisdiction pursuant to 28 U.S.C. § 1331. The court has pendent jurisdiction over state law trademark and unfair competition claims. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391.

Standards for Granting Preliminary Injunction

2. A party seeking a preliminary injunction must establish:
(a) That it has no adequate recourse at law and will suffer irreparable harm if relief is not granted;
(b) That the irreparable harm it would suffer if preliminary relief is denied out-weighs the irreparable harm defendants would suffer from the granting of such relief;
(c) That it has some likelihood of success on the merits; and
(d) That an injunction would not disserve the public interest.

United States v. Rural Electric Convenience Cooperative Co., 922 F.2d 429, 432 (7th Cir.1991); *American Hospital Supply Corp. v. Hospital Products, Ltd.*, 780 F.2d 589, 604 (7th Cir.1986).

I. *Likelihood of Success*

A. *Unfair Competition under Section 43(a) (Count II)*

3. Plaintiff's principal claim is for violation of section 43(a) of the Lanham Trademark Act, 15 U.S.C. § 1125(a), as amended. That section provides:
***12** (a) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-
(1) Is likely to cause confusion, or to cause mistake or deceive as to the affiliation, connection or, association of such person with another person, or as to the origin, sponsorship or approval of his or her goods, services, or commercial activities by another person, or
(2) In commercial advertising or promotion, misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services or commercial activities,
shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

4. The Food and Drug Administration ("FDA"), and not this court, has primary jurisdiction to enforce the Food, Drug and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301*et seq.,* and the regulations promulgated thereunder by the FDA. Thus, the FDA has jurisdiction to determine whether the compound referred to here as C17 in BioZone's CAPTRIX topical analgesic complies with the requirements set forth in the 1979 and 1983 monographs governing the sale and distribution of over-the-counter external analgesics. *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) (FDA has jurisdiction in an administrative proceeding to determine whether a drug product is a "new drug" within the meaning of the Food, Drug and Cosmetic Act). The Food, Drug and Cosmetic Act has not created, nor has it implied, any private right of action or right to relief for misbranding or any other violation of that Act or FDA regulations. *Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 367-8, 370-1 (7th Cir.1976).

5. A private litigant does, however, have a private right of action under the Lanham Act for misrepresentation and false description of any goods, including goods which are governed by the FDCA

such as pharmaceuticals and foods. *See* *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.,* 720 F.Supp. 714, 716 (N.D.Ill.1989) (Bua, J.). *See also* *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.,* 938 F.2d 1544 (2nd Cir.1991) (manufacturer of over-the-counter analgesic sued competitor for false and misleading advertising under Lanham Act); *Tambrands, Inc. v. Warner-Lambert Co.,* 673 F.Supp. 1190 (S.D.N.Y.1987) (manufacturer of home pregnancy test kit brought action against competitor for false and misleading advertising); *Ciba-Geigy Corp. v. Thompson Medical Co., Inc.,* 672 F.Supp. 679 (S.D.N.Y.1985) (appetite suppressant). The FDCA or FDA regulations may be utilized in a Lanham Act action to "establish the standard or duty which defendants allegedly failed to meet." *Grove Fresh,* 720 F.Supp. at 716.

***13** 6. In order to show a right to relief for unfair competition or false advertisement under § 43(a) of the Lanham Act, plaintiff must establish: (a) that defendant made material, false, or misleading representations of fact on or in connection with goods, the containers for goods, commercial advertising, or promotion relating to its product; (b) that the misrepresented goods traveled in interstate commerce; (c) that consumers are likely to be confused, mistaken, or deceived as a consequence; and (d) that plaintiff has been, or is likely to be, damaged either by a direct diversion of sales from itself to the defendant or loss of the good will and acceptability that plaintiff's product enjoys with the buying public. *See Data Cash Systems, Inc. v. JS & A Group, Inc.,* 223 U.S.P.Q. 865, 866 (N.D.Ill.1984) (Hart, J.); *Skil Corp. v. Rockwell International Corp.,* 375 F.Supp. 777, 783 (N.D.Ill.1974).

7. Through its president, Brian Keller, BioZone admitted that it falsely labeled its CAPTRIX box, tube, and package insert as containing capsaicin. Specifically, BioZone labeled CAPTRIX as containing as its active ingredient a chemical compound of a specific empirical formula, molecular weight, chemical structure, and purity under USP standards. The active ingredient actually contained in CAPTRIX has an empirical formula, molecular weight, and chemical structure different from the active ingredient in ZOSTRIX. No standard of USP purification exists for either CAPTRIX's active ingredient or capsaicin itself. Misrepresentations as to the contents of a product are actionable under the Lanham Act. *Coca-Cola Company v. Tropicana Products, Inc.,* 690 F.2d 312, 318 (2nd Cir.1982) (false visual demonstration suggesting that orange juice contained only fresh-squeezed, unprocessed juice actionable because it is "clearly a misrepresentation as to that product's inherent quality or characteristic"). Mr. Keller's admissions make it highly probable that Plaintiff will be successful in proving at trial that BioZone's representations are literally false.

8. BioZone's mislabeling of CAPTRIX violates relevant provisions of the Food, Drug and Cosmetics Act. BioZone's false representation regarding CAPTRIX's active ingredient violates 21 U.S.C. § 352(a), which requires that labels not be false or misleading in any particular, and 21 U.S.C. § 352(e), which requires that the label bear the common name of the drug.

9. Where a manufacturer makes an advertising claim shown to be literally false, the court may enjoin use of the claim "without reference to the advertisement's impact on the buying public." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.,* 938 F.2d 1544, 1549 (2nd Cir.1991) (quoting *Coca-Cola Co. v. Tropicana Products, Inc.,* 690 F.2d 312, 317 (2nd Cir.1982)).

10. Plaintiff is not required to show that customers were actually confused or deceived; where a claim is false on its face, the court may grant injunctive relief on the basis of its own conclusion that the challenged representations have the "tendency to deceive." *Stiffel Co. v. Westwood Lighting Group,* 658 F.Supp. 1103, 1111 (D.N.J.1987); *Skil Corp. v. Rockwell International Corp.,* 375 F.Supp. 777, 783 (N.D.Ill.1974); *PPX Enterprises, Inc. v. Audiofidelity Enterprises, Inc.,* 818 F.2d 266, 272 (2nd Cir.1987). The evidence here supports the conclusion that BioZone's representation-that capsaicin is the active ingredient in CAPTRIX-has the tendency to deceive doctors and pharmacists to believe that the product does in fact contain that ingredient. Although physicians and pharmacists are a well-informed and sophisticated audience, *see* *Plough, Inc. v. Johnson & Johnson Baby Products, Co.,* 532 F.Supp. 714, 717-18 (D.Del.1982), expert testimony in this case, as well as common sense, support the conclusion that Defendant's concealment of its active ingredient prevents even these sophisticated professionals from learning the true identity of the active ingredient. *See*

Johnson & Johnson v. GAC Int'l, Inc., 862 F.2d 975, 979-80 (2nd Cir.1988) (orthodontists might well be deceived by mislabeled materials used in orthodontic brackets). Similarly, expert testimony here supports the notion that the decision of a doctor or pharmacist to recommend a particular over-the-counter drug depends upon his or her knowledge of the drug's active ingredient. Accordingly, representations as to the identity of the ingredient are necessarily material. The survey performed by Defendant here-more specifically, telephone interviews with ten physicians-itself demonstrates that a representation that CAPTRIX contains the same active ingredient as ZOSTRIX would influence a physician's recommendation that his or her patient purchase the CAPTRIX product.

***14** 11. Section 43(a) of the Lanham Act prohibits not only false labeling or misidentification of a product but also false representations in advertising. *Data Cash Systems, Inc. v. JS & A Group, Inc.*, 223 U.S.P.Q. 865, 866 (N.D.Ill.1984) (Hart, J.); *Upjohn Co. v. Riahom Corp.*, 641 F.Supp. 1209, 1222 (D.Del.1986). A product claim is false under the Lanham Act "if the representations cite tests or other authority that does not substantiate the claim made." *Alpo Petfoods, Inc. v. Ralston Purina Co.*, 720 F.Supp. 194, 213 (D.D.C.1989), *aff'd in part, rev'd in part on other grounds,* 913 F.2d 958 (D.C.Cir.1990). Representations found to be unsupported by accepted authority or research may be deemed false on their face and actionable under § 43(a). *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2nd Cir.1991) (quoting *Alpo Petfoods, Inc.*, 720 F.Supp. at 213).

12. Plaintiff here has met its burden of showing that Defendant has made false statements regarding surveys and clinical tests by demonstrating that in fact no surveys, no clinical trials, and no tests have been performed on CAPTRIX. In *McNeil-P.C.C., supra,* the court found that plaintiff had met the burden of proving the falsity of defendant's advertising claims simply by showing that defendant's own studies did not support its claims. Here, likewise, Plaintiff's proof of the absence of any tests, clinical trials, and surveys establishes that BioZone's representations regarding CAPTRIX's characteristics-representations which could only be authenticated or verified by such tests-were false when made. Where Defendant lacked clinical proof of its representations, its predictions regarding any particular results from use of its product are false and deceptive. *See Ciba-Geigy Corp. v. Thompson Medical Co., Inc.*, 672 F.Supp. 679, 690-91 (S.D.N.Y.1985) (enjoining marketer of appetite control products from making claims of superior efficacy where such claims were not supported by well-controlled clinical tests). *See also Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2nd 222, 228 n. 7 (3rd 1990) ("completely unsubstantiated advertising claims" may be "literally false because the advertiser has absolutely no grounds for believing its claim is true"); *Upjohn Co. v. Riahom Corp.*, 641 F.Supp. 1209, 1224 (D.Del.1986) (manufacturer of hair-growth product entitled to injunction against competitor that claimed its product had been clinically tested and shown safe for use where product had actually been subject to only minimal testing).

13. Defendant's misdescriptions of the specific characteristics of its product may not be excused as "mere puffery," *Stiffel Co. v. Westwood Lighting Group.*, 658 F.Supp. 1103, 1115 (D.N.J.1987) (competitor that based claims of superiority of its lamps on purported independent tests did more than simply allege simple superiority; claims therefore were not protected as "puffing"); *Smith-Victor Corp. v. Sylvania Electric Products, Inc.*, 242 F.Supp. 302, 308-09 (N.D.Ill.1965) (statements ascribing absolute qualities to defendant's product can give rise to legal liability if these statements are not true).

***15** 14. GenDerm is likely to prevail on the merits of its claim that CAPTRIX contains an unapproved chemical compound as its active ingredient and that its distribution violates the Food Drug & Cosmetic Act. *See* 21 U.S.C. § 331(d), 355(a). BioZone's marketing of CAPTRIX constitutes unfair competition; without conducting tests or seeking FDA approval of its own product, BioZone falsely holds out CAPTRIX as containing the same active ingredient that is used in ZOSTRIX and thus exploits GenDerm's costly testing and approval effort by selling CAPTRIX at a lower price.

B. *Illinois Deceptive Trade Practices Act (Count IV)*

15. The Illinois Uniform Deceptive Trade Practices Act, Ill.Rev.Stat. ch. 121 1/2 , para. 311*et seq.* (1989), provides a cause of action for injunctive relief

to a competitor that is or may be harmed by the deceptive trade practices of another. *Greenberg v. United Airlines,* 206 Ill.App.3d 40, 46, 563 N.E.2d 1031, 1036-37 (1st Dist.1990), *app. denied,*137 Ill.2d 664, 571 N.E.2d 148 (1991); *Pain Prevention Lab, Inc. v. Electronic Waveform Labs, Inc.,* 657 F.Supp. 1486, 1493 (N.D.Ill.1987); *Brooks v. Midas-International Corp.,* 47 Ill.App.3d 266, 274-75, 361 N.E.2d 815, 821 (1st Dist.1977).

16. To prevail in an action under the Illinois Uniform Deception Trade Practices Act, plaintiff need not prove actual confusion or misunderstanding on the part of the consuming public. GenDerm has shown it is likely to prevail on the merits of its claims against BioZone under the Act in the following respects: (a) Under the Act, a person engages in a deceptive practice when he "represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have...." Ill.Rev.Stat. ch. 121 1/2 , para. 312(5). BioZone has violated this section of the Act (i) by falsely representing CAPTRIX's active ingredient; and (ii) by public characterizing the results of a ten-physician interview as "survey" results and promoting results of clinical tests which were never performed; (b) The Act is also violated when a person "represents that goods or services are a particular standard, quality or grade ... if they are of another." Ill.Rev.Stat. ch. 121 1/2 , para. 312(7). BioZone has violated this section of the Act by falsely representing that the active ingredient in CAPTRIX was "purified, USP" when no such standard exists. Further, by mislabeling the active ingredient and invoking comparisons with ZOSTRIX, BioZone represents CAPTRIX as having properties identical to ZOSTRIX.

C. *Trademark Infringement (Count I)*

17. The Lanham Trademark Act, 15 U.S.C. § 1051*et seq.,* provides a cause of action to the holder of a registered trademark against a party whose allegedly infringing mark "is likely to cause confusion, or to cause mistake, or to deceive." 15 U.S.C. § 1114(a). Plaintiff need not demonstrate actual instances of confusion or deception; instead, the court may make a factual determination by considering a variety of factors. *Union Carbide Corp. v. Ever-Ready Inc.,* 531 F.2d 366, 381-83 (7th Cir.), *cert. denied,*429 U.S. 830 (1976); *CPC Int'l, Inc. v. Caribe Food Distributors,* 731 F.Supp. 660, 664 (D.N.J.1990); *McNeil Labs., Inc. v. American Home Products Corporation,* 416 F.Supp. 804, 806 (D.N.J.1976).

***16** 18. The court's conclusion on the likelihood of confusion is a finding of fact. *Forum Corp. of North America v. Forum, Ltd.,* 903 F.2d 434, 438 (7th Cir.1990). The Seventh Circuit has identified seven specific factors:
The degree of similarity between the marks in appearance and suggestion; the similarity of the products for which the name is used; the area and manner of concurrent use; the degree of care likely to be exercised by consumers; the strength of the complainant's mark; actual confusion; and an intent on the part of the alleged infringer to palm off his products as those of another.

McGraw-Edison Co. v. Walt Disney Productions, 787 F.2d 1163, 1167-68 (7th Cir.1986). Three of these factors-the similarity of the marks, defendant's intent, and evidence of actual confusion-are deemed the more important ones. *Ziebart International Corp. v. After Market Associates, Inc.,* 802 F.2d 220, 226 (7th Cir.1986).

19. Defendant BioZone, as the second entrant into the ethical topical analgesic market, bears the responsibility of choosing a mark which will avoid confusion. *Forum Corp.,* 903 F.2d at 440-41 (reversing denial of injunctive relief where trial court placed burden on plaintiff, which was first in the marketplace). This responsibility falls upon the subsequent entrant because, as courts have observed:
It is so easy for the honest business man, who wishes to sell his goods upon their merits, to select from the entire material universe, which is before him, symbols, marks and coverings which by no possibility can cause confusion between his goods and those of his competitors, that the courts look with suspicion upon one who, in dressing his goods for the market, approaches so near to his successful rival that the public may fail to distinguish between them.

McNeil Labs., Inc. v. American Home Products Corp., 416 F.Supp. 804, 807 (D.N.J.1976) (quoting *Florence Mfg. Co. v. J.C. Dowd & Co.,* 178 F. 73, 75 (2nd Cir.1910) (finding mark "Extranol" confusingly similar to "Tylenol").

20. Some authorities suggest that a lower threshold of

actionable confusion is appropriate in cases involving pharmaceuticals. *See, e.g.,* *Morgenstern Chem. Co. v. G.D. Searle & Co.*, 253 F.2d 390, 393 (3d Cir.) (quoting *Cole Chem. Co. v. Cole Labs*, 118 F.Supp. 612, 616-17 (E.D.Mo.1954)), *cert. denied*, 358 U.S. 816 (1958). Indeed, in cases involving pharmaceutical products, the courts have concluded that the use of an identical suffix-such as "-TRIX" in this case-is likely to cause confusion. *See* *G.D. Searle & Co. v. Chas. Pfizer & Co.*, 265 F.2d 385, 388-89 (7th Cir.), *cert. denied*, 361 U.S. 819 (1959) ("Dramamine" and "Bonamine" confusingly similar); *Pennwalt Corp. v. Becton, Dickinson & Co.*, 434 F.Supp. 758, 761-63 (D.N.J.1977) ("Jockex" and "Cruex" confusingly similar); *McNeil Labs., Inc.*, 416 F.Supp. at 806-07 ("Extranol" and "Tylenol"); *but see* *Reedco, Inc. v. Hoffman-La Roche, Inc.*, 667 F.Supp. 1072, 1079-80 (D.N.J.1987) (declining to adopt *Morgenstern's* lower threshold; no showing of likelihood of confusion between over-the-counter psoriasis medication "Tegrin" and prescription psoriasis drug "Tegison").

***17** 21. Factors supporting a finding of likely confusion here include the following. The marks share a common suffix and are pronounced similarly. Both appear on boxes of similar size, against a white background, and in close proximity to the words "Cream," "Topical Analgesic," and "(Capsaicin 0.025% w/w)." The products themselves are essentially identical in color and texture; although ZOSTRIX has a tamper-proof seal, both products are white vanishing creams. The two products are designed for identical use, which is a particularly important factor in the context of medicinal goods, *Syntex Labs., Inc. v. Norwich Pharmacal Co.*, 437 F.2d 566, 569 (2d Cir.1971). Factors gravitating against a conclusion of likelihood of confusion include the absence of evidence regarding either the strength of GenDerm's mark or instances of actual confusion.[FN4] Further, customers purchasing a product such as ZOSTRIX or CAPTRIX (ordinarily on a physician's recommendation) are likely to exercise a high degree of care and to seek the assistance of a pharmacist. Perhaps most important, however, the evidence here shows that Brian Keller knew of ZOSTRIX at the time he selected the CAPTRIX mark. BioZone intended for CAPTRIX to be a "branded substitution for ZOSTRIX." Even a comparatively weak trademark is entitled to protection against manufacturers producing similar goods for similar purposes. *Cf.* *Victory Pipe Craftsmen, Inc. v. Faberge, Inc.*, 582 F.Supp. 551, 557 (N.D.Ill.1984). GenDerm has shown a likelihood of success on the merits of its trademark infringement claim.

D. *Common Law Unfair Competition and Illinois Trademark Claim (Counts III and IV)*

22. GenDerm's common law unfair competition claim (Count III) and its claim under the Illinois anti-dilution provision, Ill.Rev.Stat. ch. 140, para. 22 (1989), (Count IV), are "absorbed in a finding" in GenDerm's favor on the trademark infringement claim (Count I). *James Burrough Ltd. v. Sign of Beefeater, Inc.*, 540 F.2d 266, 274-75 n. 16 (7th Cir.1976).[FN5] Discussion of these claims is therefore unnecessary, *id.,* and GenDerm has shown it is likely to prevail on the merits of those claims, as well.

E. *Claim of Unfair Competition under California Law (Count VI)*

23. "Unfair competition" is prohibited by California law. Section 17200 of the California Business and Professions Code prohibits "unlawful, unfair or fraudulent business practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by [Section 17500 of the Code]." Section 17500, in turn, prohibits any "false or misleading statements" made to promote the sale of a product or service. Cal.Bus. & Prof.Code §§ 17200, 17500 (West 1987). California law provides a private cause of action for injunctive relief against violations of these provisions, §§ 17203, 17535, and case law demonstrates that competitors, too, may avail themselves of such a cause of action. *See* *Chronicle Publishing Co. v. Chronicle Publications, Inc.*, 733 F.Supp. 1371, 1380-81 (N.D.Cal.1989); *Century 21 Real Estate Corp. v. Sandlin*, 846 F.2d 1175, 1180-81 (9th Cir.1988).

***18** 24. To recover under § 17500, plaintiff need only show that members of the public are likely to be deceived. *People v. Dollar Rent-A-Car Sys., Inc.*, 211 Cal.App.3d 119, 129, 259 Cal.Rptr. 191, 197 (1st Dist.1989). Proof of actual deception, reasonable reliance, and damages are unnecessary. *Committee on Children's Television, Inc. v. General Foods Corp.*, 35 Cal.3d 197, 211, 673 P.2d 660, 668, 197 Cal.Rptr. 783, 791 (Cal.1983).

25. In granting an injunction in *Chronicle Publishing,* the court characterized a claim of unfair competition under § 17200 as "virtually identical" to a claim under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). 733 F.Supp. at 1380. Similarly, evidence establishing that defendant adopted a trade name sufficiently similar to plaintiff's to create a "likelihood of confusion" under federal law supports a finding that plaintiff should prevail under § 17500. *Cf. Chronicle Publishing,* 733 F.Supp. at 1381. GenDerm has demonstrated a likelihood of success on the merits of its California state law claims.

II. *Irreparable Injury*

26. Under both the Lanham Act and the Illinois Uniform Deceptive Trade Practices Act, the court may presume that irreparable injury will result where there is a likelihood of proving consumer confusion. *See Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.,* 815 F.2d 500, 505 (8th Cir.1987); *Bonner v. Westbound Records, Inc.,* 49 Ill.App.3d 543, 551, 364 N.E.2d 570, 576 (1st Dist.1977). Further, where, as here, a defendant's representations are literally false, irreparable injury is presumed. *Coca-Cola Co. v. Tropicana Products, Inc.,* 690 F.2d 312, 317-318 (2nd Cir.1982); *Tambrands, Inc. v. Warner-Lambert Co.,* 673 F.Supp. 1190, 1195 (S.D.N.Y.1987).

27. Even without the benefit of the presumption, GenDerm has established that BioZone's representations are likely to cause irreparable injury. GenDerm has presented a reasonable basis for such a conclusion, *see Johnson & Johnson v. Carter-Wallace, Inc.,* 631 F.2d 186, 190 (2nd Cir.1980); GenDerm and BioZone are the only direct competitors in the ethical topical analgesic market, and any sales of CAPTRIX correspondingly result in a loss of sales of ZOSTRIX.

28. Moreover, the mislabeling of CAPTRIX induces doctors and pharmacists to believe that this product is the same as ZOSTRIX. If CAPTRIX does not provide effective relief or causes unintended side effects, doctors and pharmacists are likely to conclude that ZOSTRIX will share the same shortcomings. Such circumstances support the conclusion that BioZone's deceptive claims will deny GenDerm part of the legitimate market for GenDerm's tested product, *see Upjohn Co. v. Riahom Corp.,* 641 F.Supp. 1209, 1225 (D.Del.1986), and may irreparably harm ZOSTRIX's reputation and goodwill. *Wynn Oil Co. v. American Way Service Corp.,* 943 F.2d 595, 607-08 (6th Cir.1991); *Premier Dental Products Co. v. Darby Dental Supply Co.,* 794 F.2d 850, 859 (3d Cir.), *cert. denied,*479 U.S. 950 (1986).

III. *Balance of Equities*

***19** 29. A balance of the equities favors Plaintiff. For several years, GenDerm has spent millions of dollars in advertising and promotion costs and in educating physicians and pharmacists. It has conducted numerous clinical tests. The time and money spent by a manufacturer in developing a product may properly be considered when assessing the balance of equities. *Upjohn Co.,* 641 F.Supp. at 1225. In contrast, here as in *Upjohn,*"defendants have invested next to nothing in the discovery and development of their product." *Id.* Some authority suggests that enjoining further production of a new product, before it has attained success, may be a "kindness" in that the enjoined party is spared potential further challenges to its mark. *See Bertolli USA, Inc. v. Filippo Bertolli Fine Foods, Ltd.,* 662 F.Supp. 203, 206 (S.D.N.Y.1987) (quoting *George Washington Mint, Inc. v. Washington Mint, Inc.,* 349 F.Supp. 255, 263 (S.D.N.Y.1972)). In any event, BioZone's owners knew at the time they marketed CAPTRIX that the product's active ingredient was not what they represented it to be. They therefore acted at their peril that such marketing would be enjoined. *See Atari, Inc. v. North American Philips Consumer Electronics Corp.,* 672 F.2d 607, 620 (7th Cir.), *cert denied,*459 U.S. 880 (1982); *Helene Curtis Indus., Inc. v. Church & Dwight Co., Inc.,* 560 F.2d 1325, 1333-34 (7th Cir.1977).

IV. *Public Interest*

30. The public interest will not be disserved by entry of a preliminary injunction. To the contrary, a strong public interest in preventing misleading advertisements, particularly with respect to pharmaceutical products, supports injunctive relief. *American Home Prods. Corp. v. Johnson & Johnson,* 654 F.Supp. 568, 590 (S.D.N.Y.1987); *see also SK & F, Co. v. Premo Pharmaceutical Labs,* 625 F.2d 1055, 1067 (3d Cir.1980); *American Home Prods. Corp. v. Chelsea Labs., Inc.,* 572 F.Supp. 278, 286 (D.N.J.1982), *aff'd,*722 F.2d 730 (3d Cir.1983);

Morgenstern Chem. Co. v. G.D. Searle & Co., 253 F.2d 390, 393-94 (3d Cir.), *cert. denied*, 358 U.S. 816 (1958). The public interest will be served by the grant of a preliminary injunction because consumers have a right to know what it is that they are purchasing. *C.B. Fleet Co., Inc. v. Complete Packaging Corp.*, 739 F.Supp. 393, 399 (N.D.Ill.1990) (recognizing public interest in accurate labeling of feminine hygiene products). Although the public interest in competitive pricing permitted the manufacture and distribution of an imitation designer perfume in *Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 505 (8th Cir.1987), the court there concluded that the imitator could use the originator's trademark in a "truthful way" when advertising that the imitator's product was a copy, so long as such use was unlikely to create confusion in the consumer's mind as to the source of the product being sold. *Id.* at 503. BioZone, here, however, has not truthfully informed the public as to the actual contents of its product and, consequently, its advertising is likely to create confusion in the minds of consumers.

V. *Unclean Hands*

***20** 31. BioZone has challenged GenDerm's standing to seek the equitable relief of a preliminary injunction on the grounds that GenDerm itself is in violation of FDA regulations and therefore has "unclean hands." Specifically, BioZone points out that GenDerm is marketing ZOSTRIX for the "relief following shingles (herpes zoster)," although the FDA has not approved ZOSTRIX for this use. Further, BioZone notes GenDerm's stipulation that dihydrocapsaicin is present in ZOSTRIX. Finally, BioZone suggests it was somehow improper for Dr. Bernstein to develop a commercial product that utilizes a compound he studied with the benefit of university research facilities and support. These circumstances do not show that GenDerm has unclean hands by " 'clear, unequivocal and convincing' evidence," as is required to bar GenDerm's claim for relief under the Lanham Act. *American Home Prods. Corp. v. Johnson & Johnson*, 654 F.Supp. 568, 590 (S.D.N.Y.1987) (declining to recognize unclean hands defense against plaintiff seeking injunction against false advertising of aspirin) (quoting *Nike, Inc. v. Rubber Mfrs. Ass'n, Inc.*, 509 F.Supp 919, 926 (S.D.N.Y.1981)). With respect to the claim that ZOSTRIX is being marketed for an unapproved use, GenDerm has demonstrated that its good faith reliance on the advice of competent counsel regarding its labeling bars use of the unclean hands defense. *See HGN Corp. v. Chamberlain, Hrdlicka, White, Johnson & Williams*, 642 F.Supp. 1443, 1454-55 (N.D.Ill.1986). Nor does the presence of dihydrocapsaicin in the CAPTRIX product taint GenDerm's claims here. Dihydrocapsaicin is a compound that occurs naturally in capsicum. Capsicum is expressly authorized for use in over-the-counter medications by the FDA monographs. GenDerm properly accounts for the presence of the dihydrocapsaicin by including sufficient quantities of the capsaicin powder so that the finished product in fact contains 0.025% capsaicin by weight. Nor has BioZone identified any impropriety in Dr. Bernstein's reliance on prior academic work in GenDerm's commercial activity. The unclean hands defense is not available to bar equitable relief.

DISCUSSION

As described more fully in the findings and conclusions set out above, GenDerm has demonstrated that it has a substantial likelihood of prevailing on the merits of its claims of false labeling and false advertising claims under the Lanham Act, its trademark infringement claim, and its related state law claims. Perhaps most damaging to BioZone was the admission of its president, Brian Keller, of knowledge before the marketing of CAPTRIX that the product did not contain the active ingredient identified on its label and described in detail on its package insert. BioZone's representations are literally false. Although irreparable harm to GenDerm may be presumed from such literal falsity, GenDerm has gone further here and adduced expert testimony that the mislabeling may result in recommendations by pharmacists that patients purchase the lower-priced CAPTRIX out of the mistaken belief that this product is the pharmacological equivalent of ZOSTRIX. If the active ingredient in CAPTRIX is ineffective or harmful, attribution of the dissatisfaction to capsaicin (rather than to CAPTRIX's untested active ingredient) could well result in irreparable harm to ZOSTRIX's reputation and goodwill.

***21** BioZone urges that there is some evidence that its active ingredient, nonivamide, has substantially similar properties to those of capsaicin. BioZone is correct in its contention that the court is not capable of making a determination regarding the safety or

efficacy of its product. That argument, however, dooms BioZone's insistence that GenDerm must bear a burden of demonstrating that CAPTRIX is not safe and effective. The court is not capable of determining that such a burden has been met. GenDerm has proven here that BioZone's claims regarding CAPTRIX are literally false. There are no scientific studies on human subjects comparing (1) nonivamide to a placebo; (2) nonivamide to capsaicin; or (3) CAPTRIX to ZOSTRIX. This proof is adequate to support injunctive relief.

GenDerm has suggested that the court seek an advisory opinion from the FDA regarding the acceptability of BioZone's use of nonivamide, pursuant to section 10.85 of the Administrative Practices and Procedures for the Department of Health and Human Services, 21 C.F.R. § 10.85(1991). Although the regulation does authorize a request for an advisory opinion on a "matter of general applicability," subparagraph (a)(2)(iv) specifically provides that such a request may be denied if it "covers a particular product or ingredient or label and does not raise a policy issue of broad applicability...." In any event, as both parties' drug law experts acknowledged, over-the-counter drug labeling is not exclusively within the province of the FDA. Even without regard to the FDA's possible conclusions regarding whether a topical analgesic having nonivamide as its active ingredient is fairly authorized by the 1979 and 1983 monographs, this court can conclude that GenDerm has demonstrated that it is likely to prevail on the merits of its false labeling and unfair competition claims.

GenDerm is likely to prevail on its substantive claims against BioZone. Absent injunctive relief, GenDerm may suffer irreparable injury. The balance of hardships favors such relief, and an injunction is not adverse to the public interest. GenDerm's motion should be granted on the terms proposed in its draft order, except that the court need not request an advisory opinion from the FDA.

Date: June 12, 1992
/s/ REBECCA R. PALLMEYER
United States Magistrate Judge

Counsel have ten days from the date of service to file objections to this Report and Recommendation with the Honorable William T. Hart. *See*Fed.R.Civ.P. 72(b); 28 U.S.C. § 636(b)(1). Failure to object constitutes a waiver of the right to appeal. *Egert v. Connecticut General Life Ins. Co.,* 900 F.2d 1032, 1039 (7th Cir.1990).

FN1. It appears, based upon the supplemental filings, that BioZone seeks an opportunity to prove that its product C17 is "synthetic capsaicin." Its materials do not so show. Moreover, this contention was expressed to the court when a temporary restraining order was denied. It was largely because counsel represented in court that BioZone's product was a cheaper equivalent that this court declined to grant a restraining order.

FN1. Simultaneously with its Proposed Findings of Fact and Conclusions of Law, Defendant BioZone has submitted a motion that the court take judicial notice of certain patents. That motion has not formally been referred to the Magistrate Judge, nor has Plaintiff responded. After this decision had been drafted, Defendant BioZone submitted a new label design for the court's approval. Neither the patents nor the proposed new label design have been considered in this report.

FN2. V.S. Govindarajan & M.N. Sathyanarayana, *Capsicum-Production, Technology, Chemistry, and Quality. Part V. Impact on Physiology, Pharmacology, Nutrition, and Metabolism; Structure, Pungency, Pain, and Desensitization Sequences,* 29 Critical Reviews in Food Science and Nutrition 435 (1991).

FN3. Ken Flieger, *Shingles-Or Chickenpox, Part Two,* 25 FDA Consumer 36, 40 (July-August 1991).

FN4. GenDerm did not perform a survey to determine the likelihood of confusion. In their depositions, Dr. Bernstein and Mr. Pollard did offer anecdotal hearsay evidence that, when asked whether they carried CAPTRIX cream, at least some pharmacists confused the product with ZOSTRIX.

FN5. Defendant argues that the Illinois trademark law does not provide a cause of action for competitors. Although some authorities so hold, *see* *Tower Publications, Inc. v. MTS Inc.*, 21 U.S.P.Q.2d 1303, 1305 (N.D.Ill.. 1991); *EZ Loader Boat Trailers, Inc. v. Cox Trailers, Inc.*, 746 F.2d 375, 380 (7th Cir.1984), Defendant's interpretation is not supported by the plain language of the Act. Earlier authorities, consistent with that plain language, interpret the protections of the Illinois law as broader than federal trademark law, thus authorizing relief even to a party that is not necessarily a competitor. *See* *John Morrell & Co. v. Reliable Packing Co.*, 172 F.Supp. 276, 276-77 (N.D.Ill.1959); *see also* *Alberto-Culver Co. v. Andrea Dumon, Inc.*, 466 F.2d 705, 709 (7th Cir.1972); *Polaroid Corp. v. Polaroid, Inc.*, 319 F.2d 830, 836-37 (7th Cir.1963).

N.D.Ill.,1992.
Genderm Corp. v. Biozone Laboratories
Not Reported in F.Supp., 1992 WL 220638 (N.D.Ill.)

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APPENDIX 5

Slip Copy
Slip Copy, 2007 WL 4591276 (D.N.J.)
(Cite as: 2007 WL 4591276 (D.N.J.))

Ehrhart v. Synthes (USA)
D.N.J.,2007.
Only the Westlaw citation is currently available.NOT FOR PUBLICATION
United States District Court,D. New Jersey.
Kerry EHRHART, on behalf of herself and all others similarly situated, and William Ehrhart, her husband,
Plaintiffs,
v.
SYNTHES (USA); Synthes, A.G.; ABC Corps 1-10,
Defendants.
Civil Action No. 07-01237 (SDW).

Dec. 28, 2007.

Bruce Heller Nagel, Nagel Rice, LLP, Roseland, NJ, for Plaintiffs.
Christopher J. Keale, Sedgwick, Detert, Moran, & Arnold, LLP, Newark, NJ, for Defendants.

OPINION

WIGENTON, District Judge.
***1** Before this Court is Defendant Synthes USA's ("Synthes" or "Defendant") Motion to Dismiss, Strike, or for a More Definite Statement on Plaintiffs' Class Action Complaint ("Complaint") pursuant to Fed.R.Civ.P. 12(b)(6), (e), and (f), respectively. The Court, having considered the parties' submissions and having decided the motion without oral argument pursuant to Fed.R.Civ.P. 78, and for the reasons set forth below, **DENIES** Defendant's motion in part and **GRANTS** it in part.

I. *JURISDICTION AND VENUE*

This Court has diversity jurisdiction over Plaintiffs Kerry and William Ehrhart's ("Plaintiffs") claims pursuant to 28 U.S.C. § 1332 as the amount in controversy is $5,000,000 and diversity of citizenship exists between Defendant, Plaintiffs and members of the proposed class. Venue is proper pursuant to 28 U.S.C. § 1391(a).

II. *BACKGROUND FACTS*

Defendants collectively research, develop, manufacture, and market radius plates that are screwed directly on to bone fragments. (Compl.¶¶ 6-7.) The plates stabilize and isolate the bone fragments, allowing the bone to heal. (Compl.¶¶ 7-8.) Plaintiff is a proposed class consisting of individuals who received or had implanted Defendants' plates (the "Class"). (Compl.¶ 15.) On March 15, 2007, Plaintiff filed a Complaint alleging that Defendants "negligently manufactured, promoted, advertised, and sold" these plates to patients with fractured or broken bones while having actual or constructive knowledge that their components could cause serious injury. (Compl.¶¶ 9-10.) Plaintiffs, on behalf of themselves and the Class, allege seven separate causes of action against Defendants: (1) negligent design, manufacture, marketing, promotion, and sale (Compl.¶ 9); (2) affirmative misrepresentations and unconscionable commercial practices in violation of New Jersey's Consumer Fraud Act, N.J.S.A. 56:8-1 et. seq. (Compl.¶¶ 9, 32, 37); (3) fraudulent failure to disclose information to members of the Class, the medical community, and the U.S. Food & Drug Administration ("FDA") (Compl.¶¶ 13, 28, 42); (4) breach of express warranty (Compl.¶¶ 45-47, 51, 54); (5) breach of implied warranty (Compl.¶¶ 49-51); (6) negligence (Compl.¶¶ 53-54); and (7) establishment of a fund for treatment and medical monitoring of affected Synthes plate users (Compl.¶¶ 56-58).

Defendant Synthes, A.G. has made no appearance nor filed any response to Plaintiffs' Complaint as of this date while Defendant Synthes concurrently filed an Answer and Motion to Dismiss, Strike, or for a More Definite Statement pursuant to Fed.R.Civ.P. 12(b)(6), (e), and (f), respectively. Defendant's motion seeks, *inter alia,* five forms of relief: (1) an order striking Plaintiffs class action allegations pursuant to Fed.R.Civ.P. 12(f) (specifically ¶¶ 14-19, and all other allegations in the complaint referring to the putative Class), or alternatively, ordering pursuant to Fed. R. Civ, P. 12(e) a more definite statement of those allegations; (2) an order dismissing Counts II and III for failure to state a claim based on non-compliance with Fed.R.Civ.P. 9(b), and based on the content of Synthes' Package Insert; (3) an order dismissing Counts V and VI for failure to state a claim, or in the alternative, an order striking the counts as redundant; (4) an order striking

¶¶ 39 and 53 of the complaint to the extent that they allege that Synthes failed to provide information to the FDA; and (5) an order dismissing the complaint as to William Ehrhart ("Ehrhart') for failure to state a claim. (Def.'s Br. at 1).

III. *LEGAL STANDARD*

A. *Motion to Dismiss pursuant to Rule 12(b)(6)*

***2** The Court must review Defendant's Motion to Dismiss according to the standard set forth in Fed.R.Civ.P. 12(b)(6). The court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the Plaintiff. *Warth v. Seldin,* 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975); *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.,* 140 F.3d 478, 483 (3d Cir.1998). Generally, when reviewing a 12(b)(6) motion, the court may only consider the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the plaintiff's claims are based upon those documents. *Pension Benefit Guar. Corp. v. White Consol. Indus.,* 998 F.2d 1192, 1196 (3d Cir.1993). The court, however, may consider documents attached to, integral to, or relied upon by the complaint. *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1426 (3d Cir.1997). The court may also take judicial notice of relevant legal proceedings. *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group, Ltd. .,* 181 F.3d 410, 426 (3d Cir.1999). A complaint should be dismissed "only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint."*Trump,* 140 F.3d at 483. While the complaint is to be construed in the light most favorable to the plaintiff, the court need not accept the plaintiff's legal conclusions or draw unwarranted factual inferences. *Lewis v. ACB Bus. Serv., Inc.,* 135 F.3d 389, 405-06 (6th Cir.1998).

B. *Motion for a More Definite Statement pursuant to Rule 12(e)*

The Court must review Defendant's Motion for a More Definite Statement according to the standard set forth in Fed.R.Civ.P. 12(e).Rule 12(e) allows a party to file a motion for a more definite statement "[i]f a pleading ... is so vague or ambiguous that a party cannot reasonably be required to frame a responsive pleading ...."Fed.R.Civ.P. 12(e). Courts in this District have held, by in large, that "[m]otions for a more definite statement are disfavored, and are generally limited to remedying unintelligible, rather than insufficiently detailed, pleadings."*Briley v. City of Trenton,* 164 F.R.D. 26, 30 (D.N.J.1995). Rather than vagueness of certain pleadings, "[t]he basis for granting [a Rule 12(e)] motion is unintelligibility" and that the complaint will be deemed sufficient for purposes of Rule 12(e) so long as a defendant "is able to respond, even if only with a 'simple denial, in good faith and without prejudice'...."*K-Tronik N.A., Inc. v. Vossloh-Schwabe Matsushita,* No. 06-0729, 2006 U.S. Dist. LEXIS 28265, *12-13 (D.N.J. May 8, 2006).

C. *Motion to Strike pursuant to Rule 12(f)*

The Court must review Defendant's Motion to Strike in accordance with the standard set forth in Fed.R.Civ.P. 12(f). Initially, the Court takes notice that motions to strike are generally raised in the context of striking a defense, not affirmative claims such as Plaintiffs. Rule 12(f) of the Federal Rules of Civil Procedure provides that "the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter."Fed.R.Civ.P. 12(f)."A court possesses considerable discretion in disposing of a motion to strike under Rule 12(f)."*River Road Devel. Corp. v. Carlson Corp.,* No. 89-7037, 1990 WL 69085 at *2 (E.D.Pa. May 23, 1990).

***3** Despite Defendant's arguments to the contrary, legion cases have affirmed that motions to strike should be used sparingly, and generally are "not favored and usually will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues."*Id.;Tonka Corp. v. Rose Art Industries, Inc.,* 836 F.Supp. 200, 217-218 (D.N.J.1993); *Federal Deposit Insurance Corp. v. White,* 828 F.Supp. 304, 307 (D.N.J.1993); *Cipollone v. Liggett Group,* 789 F.2d 181, 188 (3d Cir.1986); *Glenside West Corp. v. Exxon Corp.,* 761 F.Supp. 1100, 1115 (D.N.J.1991); *U.F.C .W. Local 56 Health and Welfare Fund v. J.D.'s Market,* 240 F.R.D. 149 (D.N.J.2007)."Partly because of the practical difficulty of deciding cases

without a factual record it is well established that striking a pleading should be sparingly used by courts. It is a drastic remedy to be resorted to only when required for the purposes of justice."*Bristol-Myers Squibb Co. v. IVAX Corp.,* 77 F.Supp.2d 606, 619-620 (D.N.J.2000); *U.S. v. Rohm and Haas Co.,* 939 F.Supp. 1142, 1151 (D.N.J.1996); *J & A Realty v. City of Asbury Park,* 763 F.Supp. 85, 87 (D.N.J.1991).

A motion to strike will not be granted where the sufficiency of a defense depends on disputed issues of fact. *United States v. Marisol, Inc.,* 725 F.Supp. 833, 836 (M.D.Pa.1989); *Linker v. Custom-Bilt Mach., Inc.,* 594 F.Supp. 894, 898 (E.D.Pa.1984). Even where the facts are not in dispute, Rule 12(f) is not meant to afford an opportunity to determine disputed and substantial questions of law. *Heller Fin. Inc. v. Midwhey Powder Co.,* 883 F.2d 1286, 1295 (7th Cir.1989); *Glenside West Corp.,* 761 F.Supp. at 1115;*Marisol, Inc.,* 725 F.Supp. at 837. Our Courts will not strike a portion of pleading for want of conciseness when to do so would violate the requirement that all pleadings be so construed as to do substantial justice. *Sundholm v. Inland Steel Container Co.,* 5 F.R.D. 507, 508 (D.N.J.1946). The Court also recognizes that in ruling on a motion to strike every fact plead in the complaint is deemed admitted. *Sabatino v. Reading Co.,* 16 F.Supp. 215, 217 (D.N.J.1936); *Simmonds Aerocessories, Limited v. Elastic Stop Nut Corp. of America,* 158 F.Supp. 277, 278-279 (D.N.J.1958); *Excello Corp v. Connor,* 10 F.R.D. 288, 289 (D.N.J.1950).

V. *DISCUSSION*

A. *Defendant's Application to Dismiss/Strike Plaintiffs Class Allegations in the Complaint, or alternatively, for a More Definite Statement.*

Synthes contends that the Court should dismiss/strike Plaintiffs' class action allegations pursuant to Fed.R.Civ.P. 23 on the basis that putative application of divergent laws of multiple states destroys the class action predominance requirement, thus rendering the matter *ipso facto* unmanageable and class certification impossible. Alternatively, Synthes argues that, if the Court does not dismiss Plaintiffs' class action allegations, it is entitled to a more definite statement under Fed.R.Civ.P. 12(e) because Plaintiffs' Complaint does not properly allege nor is there a viable basis for class certification.[FN1](Def.'s Br. at 5-13).

> FN1. The Court is mindful of Synthes's arguments that challenge Plaintiffs' ability to certify a class in this case. Indeed, if Synthes's assertions are correct, Plaintiffs face challenges to their eventual motion for class certification. At this stage, the district court, when reviewing the sufficiency of a complaint has a limited role. *Rowe,* 191 F.R.D. at 405. Here, Plaintiffs have pled that there are common questions of law and fact as to all members of the class, and Plaintiffs' claims are typical of the claims of the members of the class. Thus, this Court will not dismiss Plaintiffs' class action allegations without allowing Plaintiffs to conduct discovery to meet the challenges raised by Synthes.

***4** According to Synthes, the issue of whether class allegations are sufficient can be resolved on a motion to dismiss. Fed.R.Civ.P. 23(d)(4); *General Tele. Co. v. Falcon,* 457 U.S. 147, 160, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982). Synthes contends that this Court need not wait for a class certification motion to adjudicate class issues in instances-as here,-where a court can decide such issues by looking at the facts of the complaint. According to Synthes, other courts in the District of New Jersey have stricken or dismissed class allegations at the pleading stage for lack of commonality and predominance. *Rowe v. Morgan Stanley Dean Witter,* 191 F.R.D. 398, 405 (D.N.J.1999) (the court granted defendant's motion to dismiss the class allegations holding that the claims required individualized, fact-intensive inquiries which precluded class certification.) Per Synthes, resolving Plaintiffs' class action claims will require individualized fact specific choice of law inquiries into each device user's situation, and thus, are not suitable for class treatment. (Def.'s Br. at 6-12). Plaintiffs counter by arguing that Synthes's Motion is not the proper vehicle-either generally or in this case-for deciding class certification. Plaintiffs point out that other courts in this District have held that dismissal of class action allegations is only appropriate "in those rare cases where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met."*Strzakowlski v. General Motors Corp.,* No. 04-

4740, 2005 U.S. Dist. LEXIS 18111, *26, 2005 WL 2001912 (D.N.J. Aug. 16, 2005). Instead, putative class plaintiffs are entitled to develop their claims (class or otherwise) through discovery.

This Court will deny Synthes's Motion at this stage in the litigation as premature. Fed.R.Civ.P. 23(c)(1), which governs certification of class actions, states that "[w]hen a person sues ... as a representative of a class, the court must-*at an early practicable time*-determine by order whether to certify the action as a class action."Synthes is correct that a district court may strike class action allegations prior to discovery when presented with Rule 12(b)(6) motion. *Clark v. McDonald's Corp.,* 213 F.R.D. 198, 205 (D.N.J.2003). However, other decisions in this District teach that dismissal of class certification allegations should be ordered only "in those rare cases where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met."*Id.;Strzakowlski,* 2005 U.S. Dist. LEXIS 18111 at *26, 2005 WL 2001912; *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.,* 174 F.R.D. 332, 338 (D.N.J.1997); *Andrews v. Home Depot U.S.A., Inc.,* 2005 WL 1490474 (D.N.J.2005); *Myers v. Medquist, Inc.,* 2006 WL 3751210 (D.N.J.2006). Dismissal at this stage in the litigation would not allow Plaintiffs to fully develop their claims through discovery. Indeed, the usual practice favoring pre-certification discovery derives from the fundamental premise of Fed.R.Civ.P. 12, which is that claims, including class claims, should not be dismissed on the pleadings "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."*Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).

***5** Decisions from our sister courts (and courts in a number of other jurisdictions) have made clear that dismissal of class allegations at this stage should be done rarely and that the better course is to deny such a motion because "the shape and form of a class action evolves only through the process of discovery."*Gutierrez v. Johnson & Johnson, Inc.,* No. 01-5302, 2002 U.S. Dist. LEXIS 15418, * 16, 2002 WL 34210806 (D.N.J.2002). While it is Plaintiff's burden to prove that the proposed class action satisfies each of the required elements of Rule 23(a) and one of the prerequisites of Rule 23(b), see *Baby Neal v. Casey,* 43 F.3d 48, 55 (3d Cir.1994), the "court may find it necessary ... to analyze the elements of the parties' substantive claims and review facts revealed in discovery in order to evaluate whether the requirements of Rule 23 have been satisfied."*In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.* at 338.Moreover, "[a]s a practical matter, the court's [certification decision] usually should be predicated on more information than the complaint itself affords ... [and][t]hus, courts frequently have ruled that discovery relating to the issue whether a class action is appropriate needs to be undertaken before deciding whether to allow the action to proceed on a class basis."5C Wright, Miller & Kane, Federal Practice & Procedure Civil 3d § 1785.3. At this stage in the proceedings, the Court finds that Plaintiffs have pled sufficient facts to satisfy Rule 23(a) and (b) and, as such, the Court will address Plaintiffs' class action certification on a motion for class certification made under Rule 23(c) after Plaintiffs are given the opportunity to conduct discovery on class action status.

Synthes's final argument on this point is that it is entitled to a more definite statement under Fed.R.Civ.P. 12(e) as, "it cannot tell the bases under Rule 23 on which Plaintiff intends to proceed," and consequently, "[Plaintiffs'] allegations are hopelessly garbled, leaving Synthes uncertain as to the nature of the Plaintiffs [sic] class contentions." (Def.'s Br. at 14). In light of the Rule 12(e) precedent set forth above, *infra,* the Court finds this argument is equally unpersuasive. Plaintiffs' class allegations are not so vague that Synthes cannot, in good faith and without prejudice, frame a responsive pleading (as reflected by Synthes's concurrent filing of its answer along with the instant motion). As such, Synthes's application for a more definite statement is denied.

B. *Defendant's Application to Dismiss Counts II and III of the Complaint for Failure to State a Claim/Comply with Fed.R.Civ.P. 9(b).*

Synthes next argues that the Court should dismiss Counts II and III of the Complaint sounding in fraud and fraudulent concealment/misrepresentation respectively for failure to state a claim/comply with Fed.R.Civ.P. 9(b) and purportedly due to Synthes's Package Insert negating said claims. (Def.'s Br. at 14-16).Rule 9(b) provides in pertinent part, "in all averments of fraud ..., the circumstances constituting fraud ... shall be stated with

particularity."Fed.R.Civ.P. 9(b). Plaintiffs counter by stating that they have adequately plead their claims with the requisite particularity as required under Rule 9(b). (Pls.' Br. at 21-23).

***6** The Court emphasizes that Rule 8(a) of the Fed.R.Civ.P. requires only notice pleadings which "merely requires a 'short and plain statement of the claim showing that the pleader is entitled to relief."*In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 270 (3d Cir.2006). Under these standards, Plaintiffs' claims do not satisfy Rule 8(a). In interpreting Rule 8, the Supreme Court has made clear that Rule 8(a) does not demand fact pleading nor that Plaintiffs' legal theories be set out in particularity.*Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 512, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002); *Weston v. Pennsylvania*, 251 F.3d 420, 428-30 (3d Cir.2001). Instead, Rule 8 requires only that the complaint "provide fair notice of what the plaintiff's claim is and the grounds upon which it rests."*Id.* Under this lenient standard, it is clear that dismissal under Fed.R.Civ.P. 12(b)(6) would be inappropriate. However, Plaintiffs' fraudulent concealment/misrepresentation allegations and pleadings, taken in the light most favorable to Plaintiffs, are insufficient under Rule 9(b) to give Synthes fair and particular notice of the fraud claims against them nor do they satisfy the "simplified notice pleading standard" of Rule 8.*Swierkiewicz*, 534 U.S. at 512. Therefore, the Court denies Defendant's application for dismissal, and grants Plaintiffs' request for leave to amend Counts II and III of the Complaint with particularity.

C. *Defendant's Application to Strike or Dismiss Counts V and VI of the Complaint for Failure to State a Claim or as Redundant.*

Synthes next urges the Court to dismiss Counts V and VI of the Complaint sounding in breach of implied warranty and negligence respectively for failure to state a claim under Fed.R.Civ.P. 12(b)(6) and purportedly due to both claims being redundant of Counts I and IV. (Def.'s Br. at 17-18). Plaintiff argues in opposition that Count V contains an inadvertent typographical error in Paragraph 51 and that the word "implied" should be substituted for the word "express." (Pls.' Br. at 23-24). Count V then is clearly not "redundant" of any other counts, and thus, not subject to dismissal at this juncture. Likewise, the Court finds that Count VI contains the same type of inadvertent typographical error in Paragraph 54 as Count V suffers, and thus, is also not subject to dismissal at this juncture. Despite Defendant's assertions, Count VI further does not appear to state a claim, "for fraud on the FDA" or products liability, and therefore, is distinguishable and independent of Plaintiffs' other claims as a negligence cause of action. (Def.'s Br. at 18.) Consequently, the Court denies Defendant's application to strike/dismiss Counts V and VI, and grants Plaintiffs' request for leave to amend these Counts of the Complaint to correct the referenced typographical errors.

D. *Defendant's Application to Strike Paragraphs 39 and 53 of the Complaint.*

Synthes's Motion requests the Court strike/dismiss, "those portions of Paragraphs 39 and 53 that assert 'fraud on the FDA,' as such claims are preempted by the Medical Device Act" ("MDA").*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347-353, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). (Def.'s Br. at 18-19). While Plaintiffs acknowledge that *Buckman Co.* preempts "fraud on the FDA" claims pursuant to the MDA, Plaintiffs claim they are not asserting such a claim-their claim does not arise solely from a violation of FDA requirements. Plaintiffs argue that *Buckman Co.* provides for distinguishment of their claim such that they are not subject to MDA preemption. (Pls.' Br. at 24-25). The Court concurs with Plaintiffs' argument and denies Defendant's application to strike/dismiss these paragraphs from the Complaint at this juncture. The Court relies on the symbiotic holdings on this distinction issue set forth at length and in detail in *Medtronic Inc. v. Lohr* and *Dawson v. Ciba-Geigy Corp., U.S.A.* in support of its position.*Medtronic Inc. v. Lohr*, 518 U.S. 470, 495-501, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (holding that plaintiff's products liability claims were not preempted where said claims did not solely rely on a MDA violation)); *Dawson v. Ciba-Geigy Corp., U.S.A.*, 145 F.Supp.2d 565, 573 (D.N.J.2001) (noting that the *Buckman Co.* preemption only applies where the proffered claim specifically relies on MDA regulations as an essential element of the claim as opposed to traditional state law tort remedies)).

E. *Defendant's Application to Dismiss Mr. Ehrhart's Claim(s) for Failure to State a Claim.*

***7** Synthes's final application is to have Ehrhart's putative derivate loss of consortium and companionship claim(s) dismissed by the Court. (Def.'s Br. at 19). While the Court declines to dismiss Ehrhart's potential claim(s) at this juncture as premature and unwarranted, the Court grants Plaintiffs' application for leave to amend the Complaint to specifically state Ehrhart's alleged claim(s) with particularity as he is not even mentioned in the instant Complaint. As this matter is still novel, Ehrhart is entitled to develop his potential *per quod* claim(s), especially in light of the strong precedent espoused above against dismissal/striking of claims at the initial pleading stage. As Defendant has failed to support its allegation of Ehrhart's lack of standing, the Court will decline to consider it. (Def.'s Br. at 19).

V. *CONCLUSION*

For the foregoing reasons, Defendant's Motion to Dismiss, Strike, or for a More Definite Statement pursuant to Fed.R.Civ.P. 12(b)(6), (e), (f) is **DENIED** in part and **GRANTED** in part.

SO ORDERED.

D.N.J.,2007.
Ehrhart v. Synthes (USA)
Slip Copy, 2007 WL 4591276 (D.N.J.)

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APPENDIX 6

HAce Hardware Corp. v. Marn, Inc.
N.D.Ill.,2006.
Only the Westlaw citation is currently available.
United States District Court,N.D. Illinois.
ACE HARDWARE CORPORATION
v.
MARN, INC. et al.
No. 06 C 5335.

Dec. 27, 2006.

David J. Fish, Shawn Michael Collins, The Collins Law Firm, Naperville, IL, for Ace Hardware Corporation.
Kenneth Alan Runes, Runes Law Offices, P.C., Mount Prospect, IL, for Marn, Inc. and Michael R. Arnold.

STATEMENT

AMY J. ST. EVE, District Judge.
***1** Defendants' motion to strike the complaint [11] is denied.

[For further details see text below.]

Plaintiff Ace Hardware Corporation ("Ace") brought the present breach of contract lawsuit based on diversity jurisdiction against Defendants Marn, Inc., d/b/a Arnold's Ace Hardware and Michael R. Arnold (collectively, "Defendants").*See*28 U.S.C. § 1332. Before the Court is Defendants' Motion to Strike the Complaint pursuant to Federal Rule of Civil Procedure 12(f). For the following reasons, the Court, in its discretion, denies Defendants' motion.

In their motion, Defendants contend that certain sections of Ace's Complaint are impertinent, immaterial, scandalous, and prejudicial. Rule 12(f) provides that:

Upon motion made by a party before responding to a pleading or, if no responsive pleading is permitted by these rules, upon motion made by a party within 20 days after the service of the pleading upon the party or upon the court's own initiative at any time, the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.

In general, motions to strike are disfavored, *see* *Williams v. Jader Fuel Co.*, 944 F.2d 1388, 1405-1406 (7th Cir.1991), and often squander judicial resources. *Cf.* *Custom Vehicles, Inc. v. Forest River, Inc.*, 464 F.3d 725, 728 (7th Cir.2006) (Easterbrook, J.) (in chambers); *see also* *Heller Fin., Inc. v. Midwhey Powder Co.*, 883 F.2d 1286, 1294 (7th Cir.1989) ("motions to strike potentially serve only to delay"). Motions to strike, however, are appropriate if they serve to expedite litigation. *Heller Fin.*, 883 F.2d at 1294. "The party moving to strike has the burden of showing that the challenged allegations are so unrelated to plaintiff's claim as to be devoid of merit, unworthy of consideration, and unduly prejudicial."*E & J Gallo Winery v. Morand Bros. Beverage Co.*, 247 F.Supp.2d 979, 982 (N.D.Ill.2003) (citation and internal quotation omitted). Accordingly, "motions to strike are frequently denied 'when no prejudice could result from the challenged allegations, even though the matter literally is within the category set forth in Rule 12(f).' " *Anderson v. Board of Educ.*, 169 F.Supp.2d 864, 868 (N.D.Ill.2001) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure, § 1382). The decision whether to strike allegations under Rule 12(f) is well within the Court's discretion. *E & J Gallo Winery*, 247 F.Supp.2d at 982.

Here, Defendants have failed in their burden of showing that Ace Hardware's allegations are so unrelated to its claims that they are unworthy of consideration or unduly prejudicial. *See id.*First, Defendants specifically challenge allegations made in the introductory paragraph of the Complaint which state that "Defendants have falsely accused Ace of a number of business wrongs, hoping to contrive an excuse for non-payment" as well as other allegations concerning Defendants' alleged claims concerning Ace. In short, these allegations relate to Ace's breach of contract claim by giving background information. Furthermore, although these allegations may not be necessary under the liberal notice pleading standards of Rule 8(a), they are not prejudicial. *See* *Hoffman-Dombrowski v. Arlington Int'l Racecourse, Inc.*, 11 F.Supp.2d 1006, 1009 (N.D.Ill.1998) ("Prejudice

results where the challenged allegation has the effect of confusing the issues or is so lengthy and complex that it places an undue burden on the responding party.").

***2** Next, Defendants take umbrage with Ace's use of the term *modus operandi,* which Defendants argue is a term reserved for describing a pattern of criminal behavior. As such, Defendants contend that this word choice prejudices them. Simply put, Ace's use of this term does not confuse the issues nor does it place an undue burden on Defendants' ability to respond to the Complaint. *See id.; see also Anderson,* 169 F.Supp.2d at 868.

Defendants also argue that Ace's allegations concerning another breach of contract lawsuit against Defendants are prejudicial. Specifically, Defendants argue that this other litigation has no evidentiary value or other application to the present matter and then explain why claim preclusion, issue preclusion, and Federal Rule of Evidence 608 do not apply. First, evidentiary questions are not relevant at this stage of the proceedings. *See Payton v. Rush-Presbyterian-St. Luke's Med. Ctr.,* 184 F.3d 623, 626-27 (7th Cir.1999) (plaintiff need not plead evidence). Second, these allegations do not confuse the issues or add complexity to Ace's straight-forward breach of contract Complaint. *See Hoffman-Dombrowski,* 11 F.Supp.2d at 1009. Last, the allegations concerning the other lawsuit do not prejudice Defendants. *See Anderson,* 169 F.Supp.2d at 868. Accordingly, Defendants' argument does not serve as a basis for striking these allegations from Ace's Complaint. *See In re Spiegel, Inc. Sec. Litig.,* 382 F.Supp.2d 989, 1012 (N.D.Ill.2004).

Finally, Defendants assert that Ace is also alleging Defendants' affirmative defenses, and thus Defendants are prejudiced because Ace has placed them in the position where they must adopt these defenses and/or counterclaims. The Federal Rules of Civil Procedure, however, do not require Defendants to adopt these allegations as Defendants contend. *See*Fed.R.Civ.P. 12(h), 13(a),(b). Meanwhile, Ace does not specifically reference any affirmative defenses or counterclaims in its Complaint, but instead explains the other breach of contract lawsuit against Defendants. As such, Ace's allegations do not place any undue burden on Defendants or confuse the issues. *See Hoffman-Dombrowski,* 11 F.Supp.2d at 1009.

In conclusion, although "the Complaint is arguably inartfully drafted in certain respects," the Court "is satisfied that Defendants can fairly respond to the allegations," and thus there is no basis for striking certain allegations in Ace's Complaint. *In re Spiegel,* 382 F.Supp.2d at 1012. Therefore, the Court, in its discretion, denies Defendants' motion to strike.

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